

US3492273 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:02:29

All time stamps listed in this document are displayed in GMT

US3492273

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 04:29:49

Generated On: 10 Jun 2021 08:02:29

[Participant ID](#)

US3492273

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

US3492273

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	LATINO
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Date of Informed Consent (<i>dd MMM yyyy</i>)	30 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN AUG 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)	AUG 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) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Condition	CORONARY ARTERY DISEASE
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 (4)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Condition	KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Condition	LUMBAR SPINE BULGING DISC
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 (6)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Condition	LEFT SHOULDER ROTATOR TEAR
Start date (dd MMM yyyy)	12 AUG 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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Condition	BENIGN PITUITARY GLAND TUMOR
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)	UN UNK 1978
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 1978
Stop Year (derived)	1978

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Condition	URINARY FREQUENCY OF UNKNOWN ORIGIN
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Condition	HYPERLIPIDEMIA
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)	

US3492273

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:15 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 09:15
Height (<i>xxx.x</i>)	180 cm
Weight (<i>xxx.x</i>)	113 kg
BMI (<i>xxx.x</i>)	34.87654 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	ND - Not Done
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) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

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) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

What was the date of randomization? (dd MMM yyyy) 30 SEP 2020

What was the participant's randomization number? 191400

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) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

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) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

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)	30 SEP 2020
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 09:15
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

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) 30 SEP 2020

What was the treatment time? (00:00-23:59) 10:30 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 10:30

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) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	10:15 (24 HR)
Collection date and time (derived)	30 SEP 2020 10:15

US3492273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:50	30 SEP 2020 09:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

98.0 °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 SEP 2020 10:59

PC Open Date & Time

30 SEP 2020 10:50

PC Close Date & Time

30 SEP 2020 13:20

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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 96.8 °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	30 SEP 2020 14:30
PC Open Date & Time	30 SEP 2020 14:15
PC Close Date & Time	01 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

96.9 °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

01 OCT 2020 12:55

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 12:05

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

04 OCT 2020 08:13

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 12:05

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 12:18

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 13:51

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 11:00

PC Open Date & Time

30 SEP 2020 10:50

PC Close Date & Time

30 SEP 2020 13:20

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

30 SEP 2020 14:31

PC Open Date & Time

30 SEP 2020 14:15

PC Close Date & Time

01 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

01 OCT 2020 12:56

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:06

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 08:13

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 12:05

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 12:18

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

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 ☒

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

06 OCT 2020 13:51

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 11:02
PC Open Date & Time	30 SEP 2020 10:50
PC Close Date & Time	30 SEP 2020 13:20

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 14:32
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PC Open Date & Time	30 SEP 2020 14:15
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PC Close Date & Time	01 OCT 2020 11:59
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US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

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 ☒

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 12:57
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

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 ☒

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EAB) (1725)

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:07
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

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 ☒

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 08:14
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

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
EAB) (1725)

58 of 2590

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 12:06
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

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

60 of 2590

EAB) (1725)

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 12:19
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

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 ☒

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 13:52
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3492273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3492273

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

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

US3492273

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3492273

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 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

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

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)	28 OCT 2020
Time of assessment (00:00-23:59)	09:24 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 09:24
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	11:06 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 11:06
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3492273

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3492273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

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) 28 OCT 2020

What was the treatment time? (00:00-23:59) 10:33 (24 HR)

Treatment Date and Time (derived) 28 OCT 2020 10:33

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

US3492273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

09:33 (24 HR)

Collection date and time (derived)

28 OCT 2020 09:33

US3492273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Collection date (dd MMM yyyy)			28 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:50	28 OCT 2020 09:50
Nasopharyngeal Swab 2	No		

US3492273

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 OCT 2020 11:11

PC Open Date & Time

28 OCT 2020 10:53

PC Close Date & Time

28 OCT 2020 13:23

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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 97.6 °F

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

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

PC Time Stamp	29 OCT 2020 08:07
PC Open Date & Time	28 OCT 2020 14:18
PC Close Date & Time	29 OCT 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

97.9 °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

29 OCT 2020 12:40

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 OCT 2020 16:32

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 OCT 2020 14:05

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

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

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

01 NOV 2020 12:48

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

02 NOV 2020 13:58

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

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

03 NOV 2020 13:06

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

25

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

28 OCT 2020 11:13

PC Open Date & Time

28 OCT 2020 10:53

PC Close Date & Time

28 OCT 2020 13:23

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

29 OCT 2020 08:08

PC Open Date & Time

28 OCT 2020 14:18

PC Close Date & Time

29 OCT 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

29 OCT 2020 12:40

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 OCT 2020 16:32

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 OCT 2020 14:06

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 NOV 2020 12:49

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 NOV 2020 13:58

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

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 ☒

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

03 NOV 2020 13:06

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

No ☒

Yes ☐

PC Time stamp	28 OCT 2020 11:14
PC Open Date & Time	28 OCT 2020 10:53
PC Close Date & Time	28 OCT 2020 13:23

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

No ☒

Yes ☐

PC Time stamp	29 OCT 2020 08:09
PC Open Date & Time	28 OCT 2020 14:18
PC Close Date & Time	29 OCT 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

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 ☒

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 12:41
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

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 ☒

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EAB) (1725)

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

Yes <input type="checkbox"/>	
PC Time stamp	30 OCT 2020 16:33
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

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 ☒

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 14:06
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

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 ☒

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 12:50
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

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

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EAB) (1725)

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 13:58
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

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 ☒

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

Yes <input type="checkbox"/>	
PC Time stamp	03 NOV 2020 13:07
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3492273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492273

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492273

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3492273

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 NOV 2020
Time of assessment (00:00-23:59)	08:08 (24 HR)
Vital Signs Date and Time (derived)	25 NOV 2020 08:08
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492273

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

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.

US3492273

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 NOV 2020

Collection time (00:00-23:59)

08:25 (24 HR)

Collection date and time (derived)

25 NOV 2020 08:25

US3492273

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:30:28

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT	DAY 61
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 07:46:45
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT	DAY 68
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 08:03:46
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT	DAY 75
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 09:30:07
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

DAY 82

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

18 DEC 2020 06:19:18

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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

25 DEC 2020 05:03:32

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 checked="" 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 checked="" type="radio"/> Yes <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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" 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 checked="" type="radio"/>
Date and time of submission	04 JAN 2021 12:04:03
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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

08 JAN 2021 07:56:08

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☒

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

15 JAN 2021 07:32:50

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 JAN 2021 17:30:28
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 04:30:25
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 <input type="radio"/> Yes <input checked="" 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 checked="" type="radio"/> Yes <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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" 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 checked="" type="radio"/>
Date and time of submission	05 FEB 2021 10:10:55
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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

12 FEB 2021 04:20:42

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☒

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

19 FEB 2021 06:03:00

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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

01 MAR 2021 14:04:45

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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

05 MAR 2021 04:18:25

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 05:52:26
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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

19 MAR 2021 06:38:15

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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

26 MAR 2021 06:07:46

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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

06 APR 2021 15:16:35

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 04:11:12
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 APR 2021 05:00:38

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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

Date and time of submission

23 APR 2021 05:52:38

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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

30 APR 2021 12:36:16

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐
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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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°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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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="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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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="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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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="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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐
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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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="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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐
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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 <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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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="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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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="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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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="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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 <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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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="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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐
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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐
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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 <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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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="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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐
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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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°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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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="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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐
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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐
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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 <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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐
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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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="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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 <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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 <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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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
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Patient Cloud Close Date & Time	25 OCT 2022 23:59
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US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐
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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐
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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 ☐ 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 ☐

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2022 00:01
Patient Cloud Close Date & Time	06 DEC 2022 23:59

US3492273

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:02:29

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		01 MAR 2021 14:04:26

US3492273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492273

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3492273

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:55:59

Generated On: 10 Jun 2021 08:02:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492273

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:55:59

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:55:59

Generated On: 10 Jun 2021 08:02:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492273

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:55:59

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 03:53:19

Generated On: 10 Jun 2021 08:02:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 APR 2021
Time of assessment (<i>00:00-23:59</i>)	08:10 (24 HR)
Vital Signs Date and Time (derived)	26 APR 2021 08:10
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492273

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

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.

US3492273

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 APR 2021

Collection time (00:00-23:59)

08:20 (24 HR)

Collection date and time (derived)

26 APR 2021 08:20

US3492273

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492273

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

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

US3492273

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492273

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:02:29

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"/>

US3492273

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:02:29

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3492273

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

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

Visit date (dd MMM yyyy)	19 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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US3492273

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 01:55:58

Generated On: 10 Jun 2021 08:02:29

Date of updated informed consent (dd MMM yyyy) 19 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 19 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3492273

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00-23:59)

09:03 (24 HR)

Collection date and time (derived)

19 JAN 2021 09:03

US3492273

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	08:59
Collection Date and Time (derived)	19 JAN 2021 08:59

US3492273

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 04:30:26

Generated On: 10 Jun 2021 08:02:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

AEID

Adverse event

SHOULDER PAIN FROM CAR
ACCIDENT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

6 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

7 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

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 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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PAIN FROM CAR ACCIDENT
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

AEID	
Adverse event	CAR ACCIDENT
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)	06 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)	06 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT HAD SHOULDER PAIN AND VISITED THE DOCTOR
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3492273

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

AEID

Adverse event

INCREASED NOCTURNAL
URINARY FREQUENCY

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3492273

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

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	THIS AE WAS INITIALLY GRADE 2 WHEN IT STARTED BUT PARTICIPANT WAS STARTED ON TAMSULOSIN AND ON 12/21 THE GRADE WAS UPDATED TO GRADE 1 BECAUSE THE AE IMPROVED.

US3492273

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

AEID

Adverse event

INCREASED NOCTURNAL
URGENCY

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

AEID	USA-US101-2021-MRNA-1273-P30 1000001
Adverse event	CHEST PRESSURE - RESPIRATORY/SHORTNESS OF BREATH - CARDIAC RELATED FROM PVCs
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)	30 DEC 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 DEC 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)	30 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	31 DEC 2020
Admitted to ICU?	Yes <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

	No	<input checked="" type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
Persistent or significant disability or incapacity	False	<input type="radio"/>
Congenital anomaly or birth defect	False	<input type="radio"/>
Other medically important event	False	<input type="radio"/>
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"/>
<hr/>		
Other action taken (check all that apply)		
None	False	<input type="radio"/>
Concomitant Medication	True	<input type="radio"/>
Concomitant Procedure	True	<input type="radio"/>
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		

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

PARTICIPANT WENT TO ER
WITH SHORTNESS OF BREATH
ON 30DEC2020. HISTORY OF
STEMI MAR2019 AND ACS.
NOTED TO BE IN STABLE
CONDITION WITH NORMAL
VITAL SIGNS. EKG
SIGNIFICANT FOR SINUS
RHYTHM WITH FREQUENT
PVCs. TROPONINS NEGATIVE X
3. NO CHEMICAL EVIDENCE OF
MI. ECHO STRESS TEST
SIGNIFICANT FOR DISCRETE
APICAL WALL MOTION
ABNORMALITY POST
EXERCISE. METOPROLOL
STARTED. OVERNIGHTED FOR
OBSERVATION. TO FOLLOW UP
WITH CARDIOLOGIST AS
OUTPATIENT IN 2 WEEKS.
DISCHARGED IN STABLE
CONDITION
RETURNED 18JAN FOR
ANGIOGRAM WITH STENT
PLACEMENT

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 (6)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

AEID	USA-US101-2021-MRNA-1273-P30 1000005
Adverse event	APPENDICITIS
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)	30 JAN 2021
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)	5 FEB 2021
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)	30 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	5 FEB 2021
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 (6)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

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	True
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	SUBJECT AWOKE ON 30JAN2021 WITH ABDOMINAL PAIN. DX WITH APPENDICITIS IN ER, ADMITTED AND APPENDECTOMY PERFORMED 01FEB2021. DISCHARGED 05FEB2021

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

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 (7)

Data signed: (b) (4) 26 Apr 2021 16:34:14

Generated On: 10 Jun 2021 08:02:29

AEID	USA-US101-2021-MRNA-1273-P30 1000005
Adverse event	STREPTOCOCCAL ANGINOSUS BLOOD STREAM INFECTION
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)	30 JAN 2021
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)	05 FEB 2021
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)	30 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	05 FEB 2021
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 (7)

Data signed: (b) (4) 26 Apr 2021 16:34:14

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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	True
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	POST-APPENDECTOMY, TOOK ANTIBIOTICS
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

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

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 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication DICOLOFENAC

Prophylaxis Yes ☐
No ☒

Indication PAIN FROM ARTHRITIS TO
RIGHT KNEE

Dose per administration 75

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 (1)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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 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)		
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 (2)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication PAIN FROM LEFT SHOULDER
ROTATOR TEAR

Dose per administration 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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 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)		
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 (3)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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 (3)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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 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 (4)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication PNEUMOVAX

Prophylaxis Yes ☒
No ☐

Indication PREVENTATIVE CARE

Dose per administration UNK

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

If dose unit is Other, specify UNK

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 (4)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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)		01 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)		01 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication SHINGRIX

Prophylaxis Yes ☒
No ☐

Indication PREVENTATIVE CARE

Dose per administration UNK

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

If dose unit is Other, specify UNK

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 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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)		01 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)		01 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication AMOXICILLIN

Prophylaxis Yes ☒
No ☐

Indication PRIOR TO DENTAL WORK

Dose per administration 2000

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 (6)

Data signed: (b) (4) 26 Apr 2021 16:34:15

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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)	9 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) 9 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 (7)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 0.4

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 (7)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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)		14 NOV 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 (8)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication URINARY FREQUENCY OF UNKNOWN ORIGIN

Dose per administration 0.4

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 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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)		25 NOV 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 (9)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PREVENT INFLUENZA

Dose per administration UNK

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

If dose unit is Other, specify UNK

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 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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)		23 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 NOV 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 16:34:15

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Name of Medication SHINGLES VACCINE

Prophylaxis Yes ☒
No ☐

Indication PREVENT SHINGLES

Dose per administration UNK

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

If dose unit is Other, specify UNK

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 (10)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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)	23 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) 23 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 (11)

Data signed: (b) (4) 26 Apr 2021 16:34:15

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Name of Medication METOPROLOL SUCCINATE

Prophylaxis Yes ☐
No ☒

Indication PREMATURE VENTRICULAR
CONTRACTIONS - IN RELATION
TO CHEST PRESSURE AE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 16:34:15

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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)		31 DEC 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 (12)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

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 (12)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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 (13)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication PLAVIX

Prophylaxis Yes ☐
No ☒

Indication POST-PROCEDURE STENT

Dose per administration 75

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 (13)

Data signed: (b) (4) 26 Apr 2021 16:34:15

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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)	18 JAN 2021	
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 (14)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication CRESTOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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 (14)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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)		18 JAN 2021
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 (15)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication AUGMENTIN CLAVULANIC
875/125 MG

Prophylaxis Yes ☐
No ☒

Indication POST-APPENDECTOMY
ANTIBIOTIC COVERAGE

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 (15)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
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 (16)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☒
No ☐

Indication STOOL SOFTENER

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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 FEB 2021
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"/>

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POST-OPERATIVE PAIN

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 ☐
Intraocular ☐

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EAB) (1725)

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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 FEB 2021
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"/>

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

Name of Medication PIPERACILLIN/TAZOBACTAM
(ZOSYN)

Prophylaxis Yes ☐
No ☒

Indication STREPTOCOCCAL ANGINOSUS
BLOOD STREAM INFECTION

Dose per administration 3.375

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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US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

	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)	01 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 FEB 2021	
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"/>

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 04:30:27

Generated On: 10 Jun 2021 08:02:29

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 01:55:58

Generated On: 10 Jun 2021 08:02:29

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
30 DEC 2020	EXERCISE STRESS ECHO	Adverse Event	
30 DEC 2020	EKG	Adverse Event	
30 DEC 2020	CHEST X-RAY 1 VIEW	Adverse Event	
18 JAN 2021	ANGIOGRAM WITH STENT PLACEMENT	Medical History	
1 FEB 2021	APPENDECTOMY	Adverse Event	
30 DEC 2020	ACS RULE OUT WITH TROPONIN NEGATIVE X3	Adverse Event	
30 JAN 2021	BLOOD CULTURES	Adverse Event	

US3492273

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:02:29

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3492273

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:02:29

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 ☐

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	05/JAN/2021 13:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	13/JAN/2021 10:42
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

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	29/JAN/2021 17:08
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

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	02/FEB/2021 15:17
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

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	08/FEB/2021 12:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	25/FEB/2021 20:48
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

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	02/MAR/2021 16:42
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

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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 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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	16/APR/2021 14:12
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

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/FEB/2021 12:22
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

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/FEB/2021 13:01
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

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	31/MAR/2021 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

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/APR/2021 09:33
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

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/APR/2021 14:38
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

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 16:34:15

Generated On: 10 Jun 2021 08:02:29

SAEID	USA-US101-2021-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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/APR/2021 06:14
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

US3492273 (Prod: UIC Project WISH CRS)

US3492273

Form: Participant Creation

Generated On: 10 Jun 2021 08:02:29

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:39
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:29:49
User entered 'US3492273'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 13:48:06

US3492273

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 14:02:12

US3492273

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:12
User entered '30 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 13:48:07

US3492273

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[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 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:12
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Sep 2020 14:02:12

US3492273

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'SCRN'	System	30 Sep 2020 14:02:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:15
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 13:48:08

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:15
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	01 Oct 2020 13:22:29
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 13:22:29
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	30 Sep 2020 14:03:40
User entered '66'	(b) (4), (b) (6)	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'YEARS'	System	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '65'	System	30 Sep 2020 14:03:40

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:15
User entered 'Male (M)'	(b) (4), (b) (6)	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:15
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:15
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:15
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:15
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:15
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:15
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:15
User entered 'I'	(b) (4), (b) (6)	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:15
User entered 'Latino'	(b) (4), (b) (6)	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:15
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:02:29

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:15
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:03:12

US3492273

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:19
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 14:03:40

US3492273

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'Sep 2020'	System	30 Sep 2020 14:03:40

US3492273

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '2020'	System	30 Sep 2020 14:03:40

US3492273

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:19
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	30 Sep 2020 14:03:40

US3492273

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 14:03:40

US3492273

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:19
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:03:40

US3492273

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:19
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:03:40

US3492273

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:19
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 14:03:40

US3492273

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:19
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 13:48:07

US3492273

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:02:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'I'	System	30 Sep 2020 14:03:48

US3492273

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 14:03:48

US3492273

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:02:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 12:57:28

US3492273

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 12:59:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 12:59:48
Data point term sent to Coder	System	01 Oct 2020 12:58:19
User entered 'myocardial infarction'	(b) (4), (b) (6)	01 Oct 2020 12:57:56

US3492273

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 17:11:02
Signature has been broken.	(b) (4), (b) (6)	24 Feb 2021 17:11:02
User entered 'UN Mar 2019' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Feb 2021 17:11:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'un UNK 2019'	(b) (4), (b) (6)	01 Oct 2020 12:57:56

US3492273

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 12:57:56

US3492273

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 12:57:56

US3492273

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 17:11:02
Signature has been broken.	(b) (4), (b) (6)	24 Feb 2021 17:11:02
User entered 'UN Mar 2019' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Feb 2021 17:11:02
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'un UNK 2019'	(b) (4), (b) (6)	01 Oct 2020 12:57:56

US3492273

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 12:57:56

US3492273

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'Mar 2019'	System	24 Feb 2021 17:11:02
User entered 'Jan 2019'	System	01 Oct 2020 12:57:56

US3492273

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '2019'	System	01 Oct 2020 12:57:56

US3492273

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'Mar 2019'	System	24 Feb 2021 17:11:02
User entered 'Jan 2019'	System	01 Oct 2020 12:57:56

US3492273

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '2019'	System	01 Oct 2020 12:57:56

US3492273

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 12:59:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 12:59:48
Data point term sent to Coder	System	01 Oct 2020 12:58:19
User entered 'hypertension'	(b) (4), (b) (6)	01 Oct 2020 12:58:08

US3492273

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'un Aug 2020'	(b) (4), (b) (6)	01 Oct 2020 12:58:08

US3492273

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 12:58:08

US3492273

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 12:58:08

US3492273

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:58:08

US3492273

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 12:58:08

US3492273

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'Aug 2020'	System	01 Oct 2020 12:58:08

US3492273

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '2020'	System	01 Oct 2020 12:58:08

US3492273

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 12:58:08

US3492273

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 12:58:08

US3492273

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:00:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:00:48
Data point term sent to Coder	System	01 Oct 2020 12:59:20
User entered 'coronary artery disease'	(b) (4), (b) (6)	01 Oct 2020 12:58:25

US3492273

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:58:25

US3492273

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 12:58:25

US3492273

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 12:58:25

US3492273

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:58:25

US3492273

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 12:58:25

US3492273

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 12:58:25

US3492273

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 12:58:25

US3492273

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 12:58:25

US3492273

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 12:58:25

US3492273

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:00:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:00:47
Data point term sent to Coder	System	01 Oct 2020 12:59:20
User entered 'kidney stones'	(b) (4), (b) (6)	01 Oct 2020 12:58:35

US3492273

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'un UNK 1989'	(b) (4), (b) (6)	01 Oct 2020 12:58:35

US3492273

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 12:58:35

US3492273

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 12:58:35

US3492273

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:58:35

US3492273

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 12:58:35

US3492273

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'Jan 1989'	System	01 Oct 2020 12:58:35

US3492273

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '1989'	System	01 Oct 2020 12:58:35

US3492273

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 12:58:35

US3492273

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 12:58:35

US3492273

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Intervertebral disc bulging - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 07:43:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 07:43:22
Data point term sent to Coder	System	01 Oct 2020 13:02:24
User entered 'lumbar spine bulging disc'	(b) (4), (b) (6)	01 Oct 2020 13:01:33

US3492273

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:01:33

US3492273

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 13:01:33

US3492273

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:01:33

US3492273

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:01:33

US3492273

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 13:01:33

US3492273

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 13:01:33

US3492273

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 13:01:33

US3492273

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 13:01:33

US3492273

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 13:01:33

US3492273

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 09:37:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 09:37:15
Data point term sent to Coder	System	01 Oct 2020 13:02:24
User entered 'left shoulder rotator tear'	(b) (4), (b) (6)	01 Oct 2020 13:01:49

US3492273

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered '12 Aug 2020'	(b) (4), (b) (6)	01 Oct 2020 13:01:49

US3492273

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 13:01:49

US3492273

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:01:49

US3492273

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:01:49

US3492273

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 13:01:49

US3492273

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'Aug 2020'	System	01 Oct 2020 13:01:49

US3492273

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '2020'	System	01 Oct 2020 13:01:49

US3492273

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 13:01:49

US3492273

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 13:01:49

US3492273

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User closed query 'Per DM CLR: Please update the condition to confirm if the TUMOR was benign or cancerous. 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)	06 Nov 2020 14:33:29
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms benign, HLT: Endocrine neoplasms benign NEC, PT: Pituitary tumour benign, LLT: Pituitary tumor benign - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:33:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:33:24
Data point term sent to Coder	System	29 Oct 2020 12:57:17
Query 'Per DM CLR: Please update the condition to confirm if the TUMOR was benign or cancerous. 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 'updated - benign' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:56:56
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 12:56:48
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 12:56:48
User entered 'benign PITUITARY GLAND TUMOR' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 12:56:48
User opened query 'Per DM CLR: Please update the condition to confirm if the TUMOR was benign or cancerous. 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)	26 Oct 2020 09:48:50

US3492273

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:29

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:36
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Endocrine neoplasms malignant and unspecified NEC, PT: Pituitary tumour, LLT: Pituitary tumour - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 09:22:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 09:22:40
Data point term sent to Coder	System	01 Oct 2020 13:02:23
User entered 'pituitary gland tumor'	(b) (4), (b) (6)	01 Oct 2020 13:02:15

US3492273

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:02:15

US3492273

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'l'	(b) (4), (b) (6)	01 Oct 2020 13:02:15

US3492273

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:02:15

US3492273

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered 'un UNK 1978'	(b) (4), (b) (6)	01 Oct 2020 13:02:15

US3492273

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:36
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 13:02:15

US3492273

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 13:02:15

US3492273

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	01 Oct 2020 13:02:15

US3492273

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'Jan 1978'	System	01 Oct 2020 13:02:15

US3492273

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '1978'	System	01 Oct 2020 13:02:15

US3492273

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Dec 2020 16:48:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:48:49
Data point term sent to Coder	System	11 Dec 2020 15:41:28
User entered 'arthritis of the right knee'	(b) (4), (b) (6)	11 Dec 2020 15:40:50

US3492273

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:40:50

US3492273

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:40:50

US3492273

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:40:50

US3492273

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:40:50

US3492273

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:40:50

US3492273

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'Jan 2010'	System	11 Dec 2020 15:40:50

US3492273

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '2010'	System	11 Dec 2020 15:40:50

US3492273

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	11 Dec 2020 15:40:50

US3492273

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	11 Dec 2020 15:40:50

US3492273

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Pollakiuria, LLT: Urinary frequency - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Dec 2020 13:22:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Dec 2020 13:22:43
Data point term sent to Coder	System	11 Dec 2020 15:56:40
User entered 'uRINARY FREQUENCY OF UNKNOWN ORIGIN'	(b) (4), (b) (6)	11 Dec 2020 15:55:53

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'UN UNK 2014'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:55:53

US3492273

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:55:53

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:55:53

US3492273

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:55:53

US3492273

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:55:53

US3492273

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'Jan 2014'	System	11 Dec 2020 15:55:53

US3492273

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '2014'	System	11 Dec 2020 15:55:53

US3492273

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	11 Dec 2020 15:55:53

US3492273

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	11 Dec 2020 15:55:53

US3492273

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 17:50:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 17:50:09
Data point term sent to Coder	System	27 Jan 2021 17:48:53
User entered 'Benign Prostatic Hyperplasia'	(b) (4), (b) (6)	27 Jan 2021 17:48:33

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:48:33

US3492273

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:48:33

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:48:33

US3492273

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:48:33

US3492273

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:54
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:48:33

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'Jan 2017'	System	27 Jan 2021 17:48:33

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '2017'	System	27 Jan 2021 17:48:33

US3492273

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	27 Jan 2021 17:48:33

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	27 Jan 2021 17:48:33

US3492273

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:02:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:55
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.	Coder Import (b) (4) (b) (4)	15 Apr 2021 21:11:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 21:11:01
Data point term sent to Coder	System	15 Apr 2021 21:09:01
User entered 'hyperlipidemia'	Andrea Wendrow (b) (4) (b) (4)	15 Apr 2021 21:08:49

US3492273

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:55
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	15 Apr 2021 21:08:49

US3492273

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:55
User entered 'I'	Andrea Wendrow (b) (4) (b) (4)	15 Apr 2021 21:08:49

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Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:02:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:55
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	15 Apr 2021 21:08:49

US3492273

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:55
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	15 Apr 2021 21:08:49

US3492273

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:02:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:55
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	15 Apr 2021 21:08:49

US3492273

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	15 Apr 2021 21:08:49

US3492273

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	15 Apr 2021 21:08:49

US3492273

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	15 Apr 2021 21:08:49

US3492273

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered empty.	System	15 Apr 2021 21:08:49

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:41
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:41
User entered '09:15'	(b) (4), (b) (6)	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '30 Sep 2020 09:15'	System	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:41
User entered '180' cm	(b) (4), (b) (6)	01 Oct 2020 13:17:42
DataPoint set to visible.	System	30 Sep 2020 14:03:48

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:41
User entered '113' kg	(b) (4), (b) (6)	01 Oct 2020 13:17:42
DataPoint set to visible.	System	30 Sep 2020 14:03:48

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered '34.87654'	System	01 Oct 2020 13:17:42
DataPoint set to visible.	System	30 Sep 2020 14:03:48

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'kg/m2'	System	01 Oct 2020 13:17:42
DataPoint set to visible.	System	30 Sep 2020 14:03:48

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 13:18:07
User entered '97.8' F	(b) (4), (b) (6)	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:34:59
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User closed query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 13:42:18
Query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' answered with '-----corrected-----' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:39:40
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 19:39:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 19:39:36
User opened query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 18:42:41
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:41
User entered 'Other (Other)'	(b) (4), (b) (6)	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:41
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	01 Oct 2020 13:18:07
change Data Entry Error		
User entered 'not specified'	(b) (4), (b) (6)	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:41
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	01 Oct 2020 13:18:07
change Data Entry Error		
User entered '75'	(b) (4), (b) (6)	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'bpm'	System	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:41
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	01 Oct 2020 13:18:07
change Data Entry Error		
User entered '16'	(b) (4), (b) (6)	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'breaths/min'	System	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:41
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	01 Oct 2020 13:18:07
change Data Entry Error		
User entered '129'	(b) (4), (b) (6)	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'mmHg'	System	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:41
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	01 Oct 2020 13:18:07
change Data Entry Error		
User entered '82'	(b) (4), (b) (6)	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User entered 'mmHg'	System	01 Oct 2020 13:17:42

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25

US3492273

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25

US3492273

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:17:02

US3492273

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:44
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 13:17:02

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:10:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:09:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:10:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:09:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:10:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:09:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:10:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:09:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:10:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:09:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:10:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:09:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:10:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:09:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:10:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:09:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:10:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:09:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:10:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:09:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:10:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:09:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:47
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 14:09:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:47
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:47
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:47
User entered 'I'	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:02:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:39:25
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:47
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:09:57

US3492273

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:50:30

US3492273

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:19
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 15:50:30

US3492273

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:19
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Sep 2020 15:50:30

US3492273

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'VISIT1'	System	30 Sep 2020 15:50:30

US3492273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:23
User entered '30 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 14:02:54

US3492273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:23
User entered '191400'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 14:02:54

US3492273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:23
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Sep 2020 14:02:54

US3492273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:23
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:11:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:11:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:11:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:11:16
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:11:16

US3492273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 14:11:16

US3492273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:23
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:11:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:11:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:11:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:11:16
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:11:16

US3492273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:29

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:23
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:11:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:11:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:11:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:11:16
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:11:16

US3492273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:23
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:11:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:11:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:11:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:11:16
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:11:16

US3492273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:02:29

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:23
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:11:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:11:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:11:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:11:16
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:11:16
DataPoint set to visible.	System	30 Sep 2020 14:03:40

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '09:15'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered '30 Sep 2020 09:15'	System	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '97.8' F	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered 'Other (Other)'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered 'not specified'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '75'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'bpm'	System	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '16'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'breaths/min'	System	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '129'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'mmHg'	System	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '82'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'mmHg'	System	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:02:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 14:07:51
Query 'Data is required. Please provide.' answered with 'not given' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 13:20:39
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 13:20:29
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered empty.	System	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '98.0' F	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '69'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'bpm'	System	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '18'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'breaths/min'	System	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '122'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'mmHg'	System	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:28
User entered '85'	(b) (4), (b) (6)	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'mmHg'	System	01 Oct 2020 13:20:29

US3492273

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:18:19

US3492273

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:32
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 13:18:19

US3492273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:51:38

US3492273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:36
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:51:38

US3492273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

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 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:36
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:51:38

US3492273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 15:51:38

US3492273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:36
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 15:51:38

US3492273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:36
User entered '10:30'	(b) (4), (b) (6)	30 Sep 2020 15:51:38

US3492273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered '30 Sep 2020 10:30'	System	30 Sep 2020 15:51:38

US3492273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:36
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	30 Sep 2020 15:51:38

US3492273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 19:34:36
User entered 'ONCE'	System	30 Sep 2020 15:51:38

US3492273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 15:51:38

US3492273

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:23:47

US3492273

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:42
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'PPD ran out of kits despite site ordering per requirements, PPD advised to use UV kits to replace Kit A for D1' (Site from DM).	(b) (4), (b) (6) Marla Schwarber (b) (4) (b) (4)	07 Nov 2020 15:43:11 23 Oct 2020 19:10:14
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30SEP2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:41:29
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 13:23:47

US3492273

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:42
User entered '10:15'	(b) (4), (b) (6)	01 Oct 2020 13:23:47

US3492273

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered '30 Sep 2020 10:15'	System	01 Oct 2020 13:23:47

US3492273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:02:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:54
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Nasopharyngeal Swab sample with a Collection date of 30SEP2020, however this date is presently recorded for Visit 1 Day 1. Please clarify if the Unscheduled sample collected on 30SEP2020 is actually for Visit 1 Day 1 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 09:51:47
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Nasopharyngeal Swab sample with a Collection date of 30SEP2020, however this date is presently recorded for Visit 1 Day 1. Please clarify if the Unscheduled sample collected on 30SEP2020 is actually for Visit 1 Day 1 and update as appropriate.' answered with 'PPD ran out of kits despite site ordering per requirements. PPD advised to use UV kit to replace Kit A for Day 1' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	23 Oct 2020 17:03:02
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Nasopharyngeal Swab sample with a Collection date of 30SEP2020, however this date is presently recorded for Visit 1 Day 1. Please clarify if the Unscheduled sample collected on 30SEP2020 is actually for Visit 1 Day 1 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:45:53
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 13:23:35

US3492273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Oct 2020 13:23:35

US3492273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:23:35

US3492273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:54
User entered '09:50'	(b) (4), (b) (6)	01 Oct 2020 13:23:35

US3492273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered '30 Sep 2020 09:50'	System	01 Oct 2020 13:23:35

US3492273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Oct 2020 13:23:35

US3492273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:54
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:23:35

US3492273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:54
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:23:35

US3492273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered empty.	System	01 Oct 2020 13:23:35

US3492273

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 19:34:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:51:55

US3492273

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered '1'	System	30 Sep 2020 15:51:55

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T10:59:23', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b8dd37f1-f27c-482d-931d-3df1417115ea'	System	30 Sep 2020 15:59:52
User entered 'Yes (Y)'	System	30 Sep 2020 15:59:52

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T10:59:31', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b8dd37f1-f27c-482d-931d-3df1417115ea'	System	30 Sep 2020 15:59:52
User entered '98.0'	System	30 Sep 2020 15:59:52

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T10:59:39', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b8dd37f1-f27c-482d-931d-3df1417115ea'	System	30 Sep 2020 15:59:52
User entered 'No (N)'	System	30 Sep 2020 15:59:52

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T10:59:49', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b8dd37f1-f27c-482d-931d-3df1417115ea'	System	30 Sep 2020 15:59:52
User entered '30 Sep 2020 10:59'	System	30 Sep 2020 15:59:52

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Sep 2020 10:50'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Sep 2020 13:20'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:30:01', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '73437e08-ca6d-429a-82d9-9fb4c95c6461'	System	30 Sep 2020 19:30:27
User entered 'Yes (Y)'	System	30 Sep 2020 19:30:27

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:30:13', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '73437e08-ca6d-429a-82d9-9fb4c95c6461'	System	30 Sep 2020 19:30:27
User entered '96.8'	System	30 Sep 2020 19:30:27

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:30:19', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '73437e08-ca6d-429a-82d9-9fb4c95c6461'	System	30 Sep 2020 19:30:27
User entered 'No (N)'	System	30 Sep 2020 19:30:27

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:30:26', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '73437e08-ca6d-429a-82d9-9fb4c95c6461'	System	30 Sep 2020 19:30:27
User entered '30 Sep 2020 14:30'	System	30 Sep 2020 19:30:27

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Sep 2020 14:15'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 2'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:54:57', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '6a6ec122-82aa-4524-9c0c-dadcde4a281f'	System	01 Oct 2020 17:55:44
User entered 'Yes (Y)'	System	01 Oct 2020 17:55:44

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:55:13', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '6a6ec122-82aa-4524-9c0c-dadcde4a281f' User entered '96.9'	System	01 Oct 2020 17:55:44
	System	01 Oct 2020 17:55:44

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:55:22', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '6a6ec122-82aa-4524-9c0c-dadcde4a281f'	System	01 Oct 2020 17:55:44
User entered 'No (N)'	System	01 Oct 2020 17:55:44

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:55:40', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '6a6ec122-82aa-4524-9c0c-dadcde4a281f'	System	01 Oct 2020 17:55:44
User entered '01 Oct 2020 12:55'	System	01 Oct 2020 17:55:44

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 3'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:01:37', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b743b5b7-4ce6-4853-b763-1a69b5b1633b'	System	02 Oct 2020 17:06:22
User entered 'Yes (Y)'	System	02 Oct 2020 17:06:22

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:05:31', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b743b5b7-4ce6-4853-b763-1a69b5b1633b'	System	02 Oct 2020 17:06:22
User entered '96.6'	System	02 Oct 2020 17:06:22

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:05:44', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b743b5b7-4ce6-4853-b763-1a69b5b1633b'	System	02 Oct 2020 17:06:22
User entered 'No (N)'	System	02 Oct 2020 17:06:22

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:05:58', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b743b5b7-4ce6-4853-b763-1a69b5b1633b'	System	02 Oct 2020 17:06:22
User entered '02 Oct 2020 12:05'	System	02 Oct 2020 17:06:22

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 4'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:13:04', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '873ede26-2bf5-4c59-a117-a6756cba2bf1'	System	04 Oct 2020 13:13:30
User entered 'Yes (Y)'	System	04 Oct 2020 13:13:30

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:13:14', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '873ede26-2bf5-4c59-a117-a6756cba2bf1'	System	04 Oct 2020 13:13:30
User entered '97.4'	System	04 Oct 2020 13:13:30

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:13:20', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '873ede26-2bf5-4c59-a117-a6756cba2bf1'	System	04 Oct 2020 13:13:30
User entered 'No (N)'	System	04 Oct 2020 13:13:30

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:13:27', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '873ede26-2bf5-4c59-a117-a6756cba2bf1'	System	04 Oct 2020 13:13:30
User entered '04 Oct 2020 08:13'	System	04 Oct 2020 13:13:30

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 5'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:04:38', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'a8ec8dcd-6a6c-4f46-bd66-1948ade1d8d2'	System	04 Oct 2020 17:05:08
User entered 'Yes (Y)'	System	04 Oct 2020 17:05:08

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:04:54', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'a8ec8dcd-6a6c-4f46-bd66-1948ade1d8d2'	System	04 Oct 2020 17:05:08
User entered '96.3'	System	04 Oct 2020 17:05:08

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'a8ec8dcd-6a6c-4f46-bd66-1948ade1d8d2'	System	04 Oct 2020 17:05:08
User entered 'No (N)'	System	04 Oct 2020 17:05:08

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:05:05', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'a8ec8dcd-6a6c-4f46-bd66-1948ade1d8d2'	System	04 Oct 2020 17:05:08
User entered '04 Oct 2020 12:05'	System	04 Oct 2020 17:05:08

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 6'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:16:43', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'ae77c119-f388-4b77-8e91-78ab0dc31e16'	System	05 Oct 2020 17:18:14
User entered 'Yes (Y)'	System	05 Oct 2020 17:18:14

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:17:57', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'ae77c119-f388-4b77-8e91-78ab0dc31e16'	System	05 Oct 2020 17:18:14
User entered '97.6'	System	05 Oct 2020 17:18:14

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:18:06', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'ae77c119-f388-4b77-8e91-78ab0dc31e16'	System	05 Oct 2020 17:18:14
User entered 'No (N)'	System	05 Oct 2020 17:18:14

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:18:11', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'ae77c119-f388-4b77-8e91-78ab0dc31e16'	System	05 Oct 2020 17:18:14
User entered '05 Oct 2020 12:18'	System	05 Oct 2020 17:18:14

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 7'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:50:56', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '8647063d-f2ee-457e-89f7-6fcb2eb43d7f'	System	06 Oct 2020 18:51:57
User entered 'Yes (Y)'	System	06 Oct 2020 18:51:57

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:51:04', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '8647063d-f2ee-457e-89f7-6fcb2eb43d7f' User entered '97.5'	System	06 Oct 2020 18:51:57
	System	06 Oct 2020 18:51:57

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:51:13', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '8647063d-f2ee-457e-89f7-6fcb2eb43d7f'	System	06 Oct 2020 18:51:57
User entered 'No (N)'	System	06 Oct 2020 18:51:57

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:51:19', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '8647063d-f2ee-457e-89f7-6fcb2eb43d7f' User entered '06 Oct 2020 13:51'	System	06 Oct 2020 18:51:57
	System	06 Oct 2020 18:51:57

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:00:12', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '2e225278-bdd5-4887-8920-8911cffe2c5f'	System	30 Sep 2020 16:01:23
User entered 'None (1)'	System	30 Sep 2020 16:01:23

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:00:18', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '2e225278-bdd5-4887-8920-8911cffe2c5f'	System	30 Sep 2020 16:01:23
User entered 'No (N)'	System	30 Sep 2020 16:01:23

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:00:27', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '2e225278-bdd5-4887-8920-8911cffe2c5f'	System	30 Sep 2020 16:01:23
User entered 'No (N)'	System	30 Sep 2020 16:01:23

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:00:34', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '2e225278-bdd5-4887-8920-8911cffe2c5f'	System	30 Sep 2020 16:01:23
User entered 'None (1)'	System	30 Sep 2020 16:01:23

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:00:57', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '2e225278-bdd5-4887-8920-8911cffe2c5f'	System	30 Sep 2020 16:01:23
User entered '30 Sep 2020 11:00'	System	30 Sep 2020 16:01:23

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Sep 2020 10:50'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Sep 2020 13:20'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:30:57', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b82b9078-3dc2-4b2e-b60f-7d821ffffb73'	System	30 Sep 2020 19:31:30
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 19:31:30

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:31:05', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b82b9078-3dc2-4b2e-b60f-7d821ffffb73'	System	30 Sep 2020 19:31:30
User entered 'No (N)'	System	30 Sep 2020 19:31:30

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:31:11', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b82b9078-3dc2-4b2e-b60f-7d821ffffb73'	System	30 Sep 2020 19:31:30
User entered 'No (N)'	System	30 Sep 2020 19:31:30

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:31:22', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b82b9078-3dc2-4b2e-b60f-7d821ffffb73'	System	30 Sep 2020 19:31:30
User entered 'None (1)'	System	30 Sep 2020 19:31:30

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:31:27', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b82b9078-3dc2-4b2e-b60f-7d821ffffb73'	System	30 Sep 2020 19:31:30
User entered '30 Sep 2020 14:31'	System	30 Sep 2020 19:31:30

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Sep 2020 14:15'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 2'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:56:10', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd73fed06-7961-493c-b8fa-21b76eae5d17'	System	01 Oct 2020 17:56:41
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 17:56:41

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:56:16', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd73fed06-7961-493c-b8fa-21b76eae5d17'	System	01 Oct 2020 17:56:41
User entered 'No (N)'	System	01 Oct 2020 17:56:41

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:56:23', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd73fed06-7961-493c-b8fa-21b76eae5d17'	System	01 Oct 2020 17:56:41
User entered 'No (N)'	System	01 Oct 2020 17:56:41

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:56:32', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd73fed06-7961-493c-b8fa-21b76eae5d17'	System	01 Oct 2020 17:56:41
User entered 'None (1)'	System	01 Oct 2020 17:56:41

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:56:40', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd73fed06-7961-493c-b8fa-21b76eae5d17'	System	01 Oct 2020 17:56:41
User entered '01 Oct 2020 12:56'	System	01 Oct 2020 17:56:41

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 3'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:06:08', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fa758746-b147-4ed7-84ae-a52aae071f22'	System	02 Oct 2020 17:06:29
User entered 'None (1)'	System	02 Oct 2020 17:06:29

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:06:12', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fa758746-b147-4ed7-84ae-a52aae071f22'	System	02 Oct 2020 17:06:29
User entered 'No (N)'	System	02 Oct 2020 17:06:29

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:06:17', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fa758746-b147-4ed7-84ae-a52aae071f22'	System	02 Oct 2020 17:06:29
User entered 'No (N)'	System	02 Oct 2020 17:06:29

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:06:21', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fa758746-b147-4ed7-84ae-a52aae071f22'	System	02 Oct 2020 17:06:29
User entered 'None (1)'	System	02 Oct 2020 17:06:29

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:06:25', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fa758746-b147-4ed7-84ae-a52aae071f22'	System	02 Oct 2020 17:06:29
User entered '02 Oct 2020 12:06'	System	02 Oct 2020 17:06:29

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 4'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:13:33', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fcec6fdc-e0e6-416a-85fc-a9473b583ebc'	System	04 Oct 2020 13:14:01
User entered 'None (1)'	System	04 Oct 2020 13:14:01

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:13:37', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fcec6fdc-e0e6-416a-85fc-a9473b583ebc'	System	04 Oct 2020 13:14:01
User entered 'No (N)'	System	04 Oct 2020 13:14:01

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:13:41', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fcec6fdc-e0e6-416a-85fc-a9473b583ebc'	System	04 Oct 2020 13:14:01
User entered 'No (N)'	System	04 Oct 2020 13:14:01

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:13:55', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fcec6fdc-e0e6-416a-85fc-a9473b583ebc'	System	04 Oct 2020 13:14:01
User entered 'None (1)'	System	04 Oct 2020 13:14:01

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:13:57', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fcec6fdc-e0e6-416a-85fc-a9473b583ebc'	System	04 Oct 2020 13:14:01
User entered '04 Oct 2020 08:13'	System	04 Oct 2020 13:14:01

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 5'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:05:12', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '725e9959-c989-4201-8958-afcf5246cba3'	System	04 Oct 2020 17:05:47
User entered 'None (1)'	System	04 Oct 2020 17:05:47

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:05:18', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '725e9959-c989-4201-8958-afcf5246cba3'	System	04 Oct 2020 17:05:47
User entered 'No (N)'	System	04 Oct 2020 17:05:47

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:05:24', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '725e9959-c989-4201-8958-afcf5246cba3'	System	04 Oct 2020 17:05:47
User entered 'No (N)'	System	04 Oct 2020 17:05:47

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:05:41', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '725e9959-c989-4201-8958-afcf5246cba3'	System	04 Oct 2020 17:05:47
User entered 'None (1)'	System	04 Oct 2020 17:05:47

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:05:44', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '725e9959-c989-4201-8958-afcf5246cba3'	System	04 Oct 2020 17:05:47
User entered '04 Oct 2020 12:05'	System	04 Oct 2020 17:05:47

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 6'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:18:25', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'f575cfff-9b1b-416c-9094-49ba0227de99'	System	05 Oct 2020 17:18:45
User entered 'None (1)'	System	05 Oct 2020 17:18:45

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:18:29', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'f575cfff-9b1b-416c-9094-49ba0227de99'	System	05 Oct 2020 17:18:45
User entered 'No (N)'	System	05 Oct 2020 17:18:45

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:18:33', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'f575cfff-9b1b-416c-9094-49ba0227de99'	System	05 Oct 2020 17:18:45
User entered 'No (N)'	System	05 Oct 2020 17:18:45

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:18:37', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'f575cfff-9b1b-416c-9094-49ba0227de99'	System	05 Oct 2020 17:18:45
User entered 'None (1)'	System	05 Oct 2020 17:18:45

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:18:41', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'f575cfff-9b1b-416c-9094-49ba0227de99'	System	05 Oct 2020 17:18:45
User entered '05 Oct 2020 12:18'	System	05 Oct 2020 17:18:45

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 7'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:51:24', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e9aa7bf7-45fe-4322-a4b8-7ce274f54a1f'	System	06 Oct 2020 18:52:09
User entered 'None (1)'	System	06 Oct 2020 18:52:09

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:51:28', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e9aa7bf7-45fe-4322-a4b8-7ce274f54a1f'	System	06 Oct 2020 18:52:09
User entered 'No (N)'	System	06 Oct 2020 18:52:09

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:51:31', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e9aa7bf7-45fe-4322-a4b8-7ce274f54a1f'	System	06 Oct 2020 18:52:09
User entered 'No (N)'	System	06 Oct 2020 18:52:09

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:51:35', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e9aa7bf7-45fe-4322-a4b8-7ce274f54a1f'	System	06 Oct 2020 18:52:09
User entered 'None (1)'	System	06 Oct 2020 18:52:09

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:51:38', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e9aa7bf7-45fe-4322-a4b8-7ce274f54a1f'	System	06 Oct 2020 18:52:09
User entered '06 Oct 2020 13:51'	System	06 Oct 2020 18:52:09

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:01:08', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b7246270-0916-481e-95b7-9c83e2a709d3'	System	30 Sep 2020 16:03:22
User entered 'None (0)'	System	30 Sep 2020 16:03:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:01:11', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b7246270-0916-481e-95b7-9c83e2a709d3'	System	30 Sep 2020 16:03:22
User entered 'None (0)'	System	30 Sep 2020 16:03:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:01:17', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b7246270-0916-481e-95b7-9c83e2a709d3'	System	30 Sep 2020 16:03:22
User entered 'None (0)'	System	30 Sep 2020 16:03:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:01:22', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b7246270-0916-481e-95b7-9c83e2a709d3'	System	30 Sep 2020 16:03:22
User entered 'None (0)'	System	30 Sep 2020 16:03:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:01:26', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b7246270-0916-481e-95b7-9c83e2a709d3'	System	30 Sep 2020 16:03:22
User entered 'None (0)'	System	30 Sep 2020 16:03:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:02:01', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b7246270-0916-481e-95b7-9c83e2a709d3'	System	30 Sep 2020 16:03:22
User entered 'None (0)'	System	30 Sep 2020 16:03:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:02:22', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b7246270-0916-481e-95b7-9c83e2a709d3'	System	30 Sep 2020 16:03:22
User entered 'No (N)'	System	30 Sep 2020 16:03:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T11:02:33', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b7246270-0916-481e-95b7-9c83e2a709d3'	System	30 Sep 2020 16:03:22
User entered '30 Sep 2020 11:02'	System	30 Sep 2020 16:03:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Sep 2020 10:50'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Sep 2020 13:20'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:31:33', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '48c91308-a547-4c53-bb1a-183c5271641d'	System	30 Sep 2020 19:32:17
User entered 'None (0)'	System	30 Sep 2020 19:32:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:31:36', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '48c91308-a547-4c53-bb1a-183c5271641d' User entered 'None (0)'	System	30 Sep 2020 19:32:17
	System	30 Sep 2020 19:32:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:31:41', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '48c91308-a547-4c53-bb1a-183c5271641d' User entered 'None (0)'	System	30 Sep 2020 19:32:17
	System	30 Sep 2020 19:32:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:31:46', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '48c91308-a547-4c53-bb1a-183c5271641d'	System	30 Sep 2020 19:32:17
User entered 'None (0)'	System	30 Sep 2020 19:32:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:31:49', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '48c91308-a547-4c53-bb1a-183c5271641d'	System	30 Sep 2020 19:32:17
User entered 'None (0)'	System	30 Sep 2020 19:32:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:31:52', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '48c91308-a547-4c53-bb1a-183c5271641d'	System	30 Sep 2020 19:32:17
User entered 'None (0)'	System	30 Sep 2020 19:32:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:32:09', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '48c91308-a547-4c53-bb1a-183c5271641d'	System	30 Sep 2020 19:32:17
User entered 'No (N)'	System	30 Sep 2020 19:32:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-09-30T14:32:15', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '48c91308-a547-4c53-bb1a-183c5271641d'	System	30 Sep 2020 19:32:17
User entered '30 Sep 2020 14:32'	System	30 Sep 2020 19:32:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Sep 2020 14:15'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 2'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:56:58', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3e1cca76-2963-49e0-9564-a750a045bb2c'	System	01 Oct 2020 17:57:51
User entered 'None (0)'	System	01 Oct 2020 17:57:51

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:57:06', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3e1cca76-2963-49e0-9564-a750a045bb2c'	System	01 Oct 2020 17:57:51
User entered 'None (0)'	System	01 Oct 2020 17:57:51

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:57:13', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3e1cca76-2963-49e0-9564-a750a045bb2c'	System	01 Oct 2020 17:57:51
User entered 'None (0)'	System	01 Oct 2020 17:57:51

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:57:22', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3e1cca76-2963-49e0-9564-a750a045bb2c'	System	01 Oct 2020 17:57:51
User entered 'None (0)'	System	01 Oct 2020 17:57:51

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:57:26', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3e1cca76-2963-49e0-9564-a750a045bb2c'	System	01 Oct 2020 17:57:51
User entered 'None (0)'	System	01 Oct 2020 17:57:51

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:57:33', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3e1cca76-2963-49e0-9564-a750a045bb2c'	System	01 Oct 2020 17:57:51
User entered 'None (0)'	System	01 Oct 2020 17:57:51

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:57:45', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3e1cca76-2963-49e0-9564-a750a045bb2c'	System	01 Oct 2020 17:57:51
User entered 'No (N)'	System	01 Oct 2020 17:57:51

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-01T12:57:49', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3e1cca76-2963-49e0-9564-a750a045bb2c'	System	01 Oct 2020 17:57:51
User entered '01 Oct 2020 12:57'	System	01 Oct 2020 17:57:51

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 3'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:06:35', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '9149437f-f05c-46a4-a1a8-aa7e8fac40e6'	System	02 Oct 2020 17:07:16
User entered 'None (0)'	System	02 Oct 2020 17:07:16

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:06:37', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '9149437f-f05c-46a4-a1a8-aa7e8fac40e6'	System	02 Oct 2020 17:07:16
User entered 'None (0)'	System	02 Oct 2020 17:07:16

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:06:41', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '9149437f-f05c-46a4-a1a8-aa7e8fac40e6'	System	02 Oct 2020 17:07:16
User entered 'None (0)'	System	02 Oct 2020 17:07:16

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:06:46', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '9149437f-f05c-46a4-a1a8-aa7e8fac40e6' User entered 'None (0)'	System	02 Oct 2020 17:07:16
	System	02 Oct 2020 17:07:16

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:06:58', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '9149437f-f05c-46a4-a1a8-aa7e8fac40e6'	System	02 Oct 2020 17:07:16
User entered 'None (0)'	System	02 Oct 2020 17:07:16

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:07:01', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '9149437f-f05c-46a4-a1a8-aa7e8fac40e6'	System	02 Oct 2020 17:07:16
User entered 'None (0)'	System	02 Oct 2020 17:07:16

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:07:10', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '9149437f-f05c-46a4-a1a8-aa7e8fac40e6'	System	02 Oct 2020 17:07:16
User entered 'No (N)'	System	02 Oct 2020 17:07:16

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-02T12:07:14', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '9149437f-f05c-46a4-a1a8-aa7e8fac40e6' User entered '02 Oct 2020 12:07'	System	02 Oct 2020 17:07:16
	System	02 Oct 2020 17:07:16

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 4'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:14:08', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'a2347aea-be77-44ea-a74f-c90545a7b443'	System	04 Oct 2020 13:14:44
User entered 'None (0)'	System	04 Oct 2020 13:14:44

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:14:11', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'a2347aea-be77-44ea-a74f-c90545a7b443'	System	04 Oct 2020 13:14:44
User entered 'None (0)'	System	04 Oct 2020 13:14:44

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:14:15', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'a2347aea-be77-44ea-a74f-c90545a7b443'	System	04 Oct 2020 13:14:44
User entered 'None (0)'	System	04 Oct 2020 13:14:44

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:14:28', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'a2347aea-be77-44ea-a74f-c90545a7b443'	System	04 Oct 2020 13:14:44
User entered 'No interference with activity (1)'	System	04 Oct 2020 13:14:44

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:14:32', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'a2347aea-be77-44ea-a74f-c90545a7b443'	System	04 Oct 2020 13:14:44
User entered 'None (0)'	System	04 Oct 2020 13:14:44

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:14:35', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'a2347aea-be77-44ea-a74f-c90545a7b443'	System	04 Oct 2020 13:14:44
User entered 'None (0)'	System	04 Oct 2020 13:14:44

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:14:39', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'a2347aea-be77-44ea-a74f-c90545a7b443'	System	04 Oct 2020 13:14:44
User entered 'No (N)'	System	04 Oct 2020 13:14:44

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T08:14:42', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'a2347aea-be77-44ea-a74f-c90545a7b443'	System	04 Oct 2020 13:14:44
User entered '04 Oct 2020 08:14'	System	04 Oct 2020 13:14:44

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 5'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:05:49', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b96454ce-6923-4ab1-a7cd-6a146185bfeb'	System	04 Oct 2020 17:06:17
User entered 'None (0)'	System	04 Oct 2020 17:06:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:05:52', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b96454ce-6923-4ab1-a7cd-6a146185bfeb'	System	04 Oct 2020 17:06:17
User entered 'None (0)'	System	04 Oct 2020 17:06:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:05:57', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b96454ce-6923-4ab1-a7cd-6a146185bfeb'	System	04 Oct 2020 17:06:17
User entered 'None (0)'	System	04 Oct 2020 17:06:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:06:01', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b96454ce-6923-4ab1-a7cd-6a146185bfeb'	System	04 Oct 2020 17:06:17
User entered 'No interference with activity (1)'	System	04 Oct 2020 17:06:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:06:04', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b96454ce-6923-4ab1-a7cd-6a146185bfeb'	System	04 Oct 2020 17:06:17
User entered 'None (0)'	System	04 Oct 2020 17:06:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:06:06', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b96454ce-6923-4ab1-a7cd-6a146185bfeb'	System	04 Oct 2020 17:06:17
User entered 'None (0)'	System	04 Oct 2020 17:06:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:06:11', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b96454ce-6923-4ab1-a7cd-6a146185bfeb'	System	04 Oct 2020 17:06:17
User entered 'No (N)'	System	04 Oct 2020 17:06:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-04T12:06:14', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b96454ce-6923-4ab1-a7cd-6a146185bfeb'	System	04 Oct 2020 17:06:17
User entered '04 Oct 2020 12:06'	System	04 Oct 2020 17:06:17

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 6'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:18:45', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3a728c34-2649-4cb8-b7b4-429e67fc20c8'	System	05 Oct 2020 17:19:14
User entered 'None (0)'	System	05 Oct 2020 17:19:14

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:18:49', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3a728c34-2649-4cb8-b7b4-429e67fc20c8'	System	05 Oct 2020 17:19:14
User entered 'None (0)'	System	05 Oct 2020 17:19:14

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:18:53', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3a728c34-2649-4cb8-b7b4-429e67fc20c8'	System	05 Oct 2020 17:19:14
User entered 'None (0)'	System	05 Oct 2020 17:19:14

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:18:56', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3a728c34-2649-4cb8-b7b4-429e67fc20c8'	System	05 Oct 2020 17:19:14
User entered 'None (0)'	System	05 Oct 2020 17:19:14

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:18:59', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3a728c34-2649-4cb8-b7b4-429e67fc20c8'	System	05 Oct 2020 17:19:14
User entered 'None (0)'	System	05 Oct 2020 17:19:14

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:19:02', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3a728c34-2649-4cb8-b7b4-429e67fc20c8'	System	05 Oct 2020 17:19:14
User entered 'None (0)'	System	05 Oct 2020 17:19:14

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:19:06', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3a728c34-2649-4cb8-b7b4-429e67fc20c8'	System	05 Oct 2020 17:19:14
User entered 'No (N)'	System	05 Oct 2020 17:19:14

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-05T12:19:09', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3a728c34-2649-4cb8-b7b4-429e67fc20c8'	System	05 Oct 2020 17:19:14
User entered '05 Oct 2020 12:19'	System	05 Oct 2020 17:19:14

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	30 Sep 2020 15:51:38
User entered 'Day 7'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:51:48', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0549cc13-f2dc-4e8c-8ef1-a6b6772a1ddb'	System	06 Oct 2020 18:52:22
User entered 'None (0)'	System	06 Oct 2020 18:52:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:51:58', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0549cc13-f2dc-4e8c-8ef1-a6b6772a1ddb'	System	06 Oct 2020 18:52:22
User entered 'None (0)'	System	06 Oct 2020 18:52:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:52:03', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0549cc13-f2dc-4e8c-8ef1-a6b6772a1ddb'	System	06 Oct 2020 18:52:22
User entered 'None (0)'	System	06 Oct 2020 18:52:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:52:06', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0549cc13-f2dc-4e8c-8ef1-a6b6772a1ddb'	System	06 Oct 2020 18:52:22
User entered 'None (0)'	System	06 Oct 2020 18:52:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:52:09', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0549cc13-f2dc-4e8c-8ef1-a6b6772a1ddb'	System	06 Oct 2020 18:52:22
User entered 'None (0)'	System	06 Oct 2020 18:52:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:52:12', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0549cc13-f2dc-4e8c-8ef1-a6b6772a1ddb'	System	06 Oct 2020 18:52:22
User entered 'None (0)'	System	06 Oct 2020 18:52:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:52:16', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0549cc13-f2dc-4e8c-8ef1-a6b6772a1ddb'	System	06 Oct 2020 18:52:22
User entered 'No (N)'	System	06 Oct 2020 18:52:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-06T13:52:19', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0549cc13-f2dc-4e8c-8ef1-a6b6772a1ddb'	System	06 Oct 2020 18:52:22
User entered '06 Oct 2020 13:52'	System	06 Oct 2020 18:52:22

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 15:51:38

US3492273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 15:51:38

US3492273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:19:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 22:53:08

US3492273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:19:23
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 22:53:08

US3492273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:19:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 22:53:08

US3492273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:19:23
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 22:53:08

US3492273

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:19:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 22:53:13

US3492273

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'I'	System	07 Oct 2020 22:53:13

US3492273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:19:43
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:35:16

US3492273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:19:43
User entered '14 Oct 2020'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:35:16

US3492273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:19:43
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:35:16

US3492273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:19:43
User entered empty.	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:35:16

US3492273

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:19:48
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:35:48

US3492273

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'I'	System	15 Oct 2020 15:35:48

US3492273

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:20:11
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	22 Oct 2020 15:28:25

US3492273

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:20:11
User entered '21 Oct 2020'	Lorna Sanchez McCann (b) (4)	22 Oct 2020 15:28:25

US3492273

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:20:11
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	22 Oct 2020 15:28:25

US3492273

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:20:11
User entered empty.	Lorna Sanchez McCann (b) (4)	22 Oct 2020 15:28:25

US3492273

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:20:14
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	22 Oct 2020 15:28:39

US3492273

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'I'	System	22 Oct 2020 15:28:39

US3492273

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 14:15:09

US3492273

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:27
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 14:15:09

US3492273

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Oct 2020 14:15:09

US3492273

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'VISIT2'	System	28 Oct 2020 14:15:09

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '09:24'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered '28 Oct 2020 09:24'	System	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '97.7' F	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '77'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'bpm'	System	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '20'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'breaths/min'	System	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '124'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'mmHg'	System	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '81'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:02:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'mmHg'	System	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '11:06'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered '28 Oct 2020 11:06'	System	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '98.3' F	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '63'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'bpm'	System	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '20'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'breaths/min'	System	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '132'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'mmHg'	System	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:34
User entered '84'	(b) (4), (b) (6)	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:02:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'mmHg'	System	29 Oct 2020 13:01:02

US3492273

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 12:59:14

US3492273

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:16
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 12:59:14

US3492273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:37:21

US3492273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:24
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:37:21

US3492273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

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 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:24
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:37:21

US3492273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'MRNA-1273 OR PLACEBO'	System	28 Oct 2020 15:37:21

US3492273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:24
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 15:37:21

US3492273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:24
User entered '10:33'	(b) (4), (b) (6)	28 Oct 2020 15:37:21

US3492273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered '28 Oct 2020 10:33'	System	28 Oct 2020 15:37:21

US3492273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:24
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	28 Oct 2020 15:37:21

US3492273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:15:24
User entered 'ONCE'	System	28 Oct 2020 15:37:21

US3492273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:02:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'INTRAMUSCULAR'	System	28 Oct 2020 15:37:21

US3492273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 13:01:22

US3492273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:29
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 13:01:22

US3492273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:29
User entered '09:33'	(b) (4), (b) (6)	29 Oct 2020 13:01:22

US3492273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered '28 Oct 2020 09:33'	System	29 Oct 2020 13:01:22

US3492273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:36
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 13:01:46

US3492273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	29 Oct 2020 13:01:46

US3492273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 13:01:46

US3492273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:36
User entered '09:50'	(b) (4), (b) (6)	29 Oct 2020 13:01:46

US3492273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered '28 Oct 2020 09:50'	System	29 Oct 2020 13:01:46

US3492273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	29 Oct 2020 13:01:46

US3492273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 13:01:46

US3492273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:36
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 13:01:46

US3492273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered empty.	System	29 Oct 2020 13:01:46

US3492273

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:15:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:37:31

US3492273

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered '1'	System	28 Oct 2020 15:37:31

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:11:24', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '9349e12f-0a13-4ef7-bdde-7ba08d046907'	System	28 Oct 2020 16:11:45
User entered 'Yes (Y)'	System	28 Oct 2020 16:11:45

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:11:30', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '9349e12f-0a13-4ef7-bdde-7ba08d046907'	System	28 Oct 2020 16:11:45
User entered '98.3'	System	28 Oct 2020 16:11:45

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:11:35', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '9349e12f-0a13-4ef7-bdde-7ba08d046907'	System	28 Oct 2020 16:11:45
User entered 'No (N)'	System	28 Oct 2020 16:11:45

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:11:38', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '9349e12f-0a13-4ef7-bdde-7ba08d046907'	System	28 Oct 2020 16:11:45
User entered '28 Oct 2020 11:11'	System	28 Oct 2020 16:11:45

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '28 Oct 2020 10:53'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '28 Oct 2020 13:23'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 1, after vaccination (at home)'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:06:57', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3a18dbbc-ebab-442c-a26c-df729eca8cae'	System	29 Oct 2020 13:07:31
User entered 'Yes (Y)'	System	29 Oct 2020 13:07:31

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:07:06', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3a18dbbc-ebab-442c-a26c-df729eca8cae'	System	29 Oct 2020 13:07:31
User entered '97.6'	System	29 Oct 2020 13:07:31

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:07:21', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3a18dbbc-ebab-442c-a26c-df729eca8cae'	System	29 Oct 2020 13:07:31
User entered 'No (N)'	System	29 Oct 2020 13:07:31

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:07:24', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '3a18dbbc-ebab-442c-a26c-df729eca8cae'	System	29 Oct 2020 13:07:31
User entered '29 Oct 2020 08:07'	System	29 Oct 2020 13:07:31

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '28 Oct 2020 14:18'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 2'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:39:49', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '4240de5d-a8d8-40d0-b10d-5e56d670ae5d'	System	29 Oct 2020 17:40:28
User entered 'Yes (Y)'	System	29 Oct 2020 17:40:28

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:40:16', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '4240de5d-a8d8-40d0-b10d-5e56d670ae5d'	System	29 Oct 2020 17:40:28
User entered '97.9'	System	29 Oct 2020 17:40:28

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:40:20', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '4240de5d-a8d8-40d0-b10d-5e56d670ae5d'	System	29 Oct 2020 17:40:28
User entered 'No (N)'	System	29 Oct 2020 17:40:28

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:40:23', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '4240de5d-a8d8-40d0-b10d-5e56d670ae5d'	System	29 Oct 2020 17:40:28
User entered '29 Oct 2020 12:40'	System	29 Oct 2020 17:40:28

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 3'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:32:07', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '179bbf36-07ec-44d7-9119-4da0e6bdf521'	System	30 Oct 2020 21:32:35
User entered 'Yes (Y)'	System	30 Oct 2020 21:32:35

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:32:23', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '179bbf36-07ec-44d7-9119-4da0e6bdf521'	System	30 Oct 2020 21:32:35
User entered '97.9'	System	30 Oct 2020 21:32:35

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:32:28', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '179bbf36-07ec-44d7-9119-4da0e6bdf521'	System	30 Oct 2020 21:32:35
User entered 'No (N)'	System	30 Oct 2020 21:32:35

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:32:31', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '179bbf36-07ec-44d7-9119-4da0e6bdf521'	System	30 Oct 2020 21:32:35
User entered '30 Oct 2020 16:32'	System	30 Oct 2020 21:32:35

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 4'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:05:24', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'f7f18148-b7b6-47cc-a468-a38a6ba308e0'	System	31 Oct 2020 19:05:49
User entered 'Yes (Y)'	System	31 Oct 2020 19:05:49

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:05:37', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'f7f18148-b7b6-47cc-a468-a38a6ba308e0'	System	31 Oct 2020 19:05:49
User entered '97.5'	System	31 Oct 2020 19:05:49

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:05:43', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'f7f18148-b7b6-47cc-a468-a38a6ba308e0'	System	31 Oct 2020 19:05:49
User entered 'No (N)'	System	31 Oct 2020 19:05:49

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:05:45', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'f7f18148-b7b6-47cc-a468-a38a6ba308e0'	System	31 Oct 2020 19:05:49
User entered '31 Oct 2020 14:05'	System	31 Oct 2020 19:05:49

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '31 Oct 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '01 Nov 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 5'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:48:31', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '6709cc15-8aa3-456f-9879-58b2878ffe8b'	System	01 Nov 2020 18:48:58
User entered 'Yes (Y)'	System	01 Nov 2020 18:48:58

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:48:44', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '6709cc15-8aa3-456f-9879-58b2878ffe8b' User entered '97.8'	System	01 Nov 2020 18:48:58
	System	01 Nov 2020 18:48:58

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:48:51', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '6709cc15-8aa3-456f-9879-58b2878ffe8b'	System	01 Nov 2020 18:48:58
User entered 'No (N)'	System	01 Nov 2020 18:48:58

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:48:53', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '6709cc15-8aa3-456f-9879-58b2878ffe8b'	System	01 Nov 2020 18:48:58
User entered '01 Nov 2020 12:48'	System	01 Nov 2020 18:48:58

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '01 Nov 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '02 Nov 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 6'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:57:37', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd8ccd402-f424-4df2-bec7-d3587cb39004'	System	02 Nov 2020 19:58:09
User entered 'Yes (Y)'	System	02 Nov 2020 19:58:09

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:57:53', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd8ccd402-f424-4df2-bec7-d3587cb39004'	System	02 Nov 2020 19:58:09
User entered '97.9'	System	02 Nov 2020 19:58:09

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:02', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd8ccd402-f424-4df2-bec7-d3587cb39004'	System	02 Nov 2020 19:58:09
User entered 'No (N)'	System	02 Nov 2020 19:58:09

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:05', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd8ccd402-f424-4df2-bec7-d3587cb39004'	System	02 Nov 2020 19:58:09
User entered '02 Nov 2020 13:58'	System	02 Nov 2020 19:58:09

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '02 Nov 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '03 Nov 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 7'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:11', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd1decf6a-c342-4477-8ff4-c07e43c0f933'	System	03 Nov 2020 19:06:33
User entered 'Yes (Y)'	System	03 Nov 2020 19:06:33

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:17', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd1decf6a-c342-4477-8ff4-c07e43c0f933'	System	03 Nov 2020 19:06:33
User entered '97.8'	System	03 Nov 2020 19:06:33

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:21', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd1decf6a-c342-4477-8ff4-c07e43c0f933'	System	03 Nov 2020 19:06:33
User entered 'No (N)'	System	03 Nov 2020 19:06:33

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:25', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd1decf6a-c342-4477-8ff4-c07e43c0f933'	System	03 Nov 2020 19:06:33
User entered '03 Nov 2020 13:06'	System	03 Nov 2020 19:06:33

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '03 Nov 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '04 Nov 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:11:47', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '98b38abe-c20c-4337-b373-1eb192f09887'	System	28 Oct 2020 16:14:01
User entered 'None (1)'	System	28 Oct 2020 16:14:01

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:11:58', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '98b38abe-c20c-4337-b373-1eb192f09887'	System	28 Oct 2020 16:14:01
User entered 'No (N)'	System	28 Oct 2020 16:14:01

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:12:08', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '98b38abe-c20c-4337-b373-1eb192f09887'	System	28 Oct 2020 16:14:01
User entered 'Yes (Y)'	System	28 Oct 2020 16:14:01

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:13:31', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '98b38abe-c20c-4337-b373-1eb192f09887'	System	28 Oct 2020 16:14:01
User entered '25'	System	28 Oct 2020 16:14:01

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:13:42', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '98b38abe-c20c-4337-b373-1eb192f09887'	System	28 Oct 2020 16:14:01
User entered 'None (1)'	System	28 Oct 2020 16:14:01

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:13:52', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '98b38abe-c20c-4337-b373-1eb192f09887'	System	28 Oct 2020 16:14:01
User entered '28 Oct 2020 11:13'	System	28 Oct 2020 16:14:01

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '28 Oct 2020 10:53'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '28 Oct 2020 13:23'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 1, after vaccination (at home)'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:07:50', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '44836f52-ea93-4d21-a506-7aad0d8f5d9c'	System	29 Oct 2020 13:08:20
User entered 'Does not interfere with activity (2)'	System	29 Oct 2020 13:08:20

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:07:54', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '44836f52-ea93-4d21-a506-7aad0d8f5d9c'	System	29 Oct 2020 13:08:20
User entered 'No (N)'	System	29 Oct 2020 13:08:20

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:07:57', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '44836f52-ea93-4d21-a506-7aad0d8f5d9c'	System	29 Oct 2020 13:08:20
User entered 'No (N)'	System	29 Oct 2020 13:08:20

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:08:10', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '44836f52-ea93-4d21-a506-7aad0d8f5d9c'	System	29 Oct 2020 13:08:20
User entered 'None (1)'	System	29 Oct 2020 13:08:20

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:08:14', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '44836f52-ea93-4d21-a506-7aad0d8f5d9c'	System	29 Oct 2020 13:08:20
User entered '29 Oct 2020 08:08'	System	29 Oct 2020 13:08:20

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '28 Oct 2020 14:18'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 2'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:40:38', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5705b446-4366-4617-8d47-c9e413382276'	System	29 Oct 2020 17:41:00
User entered 'Does not interfere with activity (2)'	System	29 Oct 2020 17:41:00

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:40:44', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5705b446-4366-4617-8d47-c9e413382276'	System	29 Oct 2020 17:41:00
User entered 'No (N)'	System	29 Oct 2020 17:41:00

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:40:48', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5705b446-4366-4617-8d47-c9e413382276'	System	29 Oct 2020 17:41:00
User entered 'No (N)'	System	29 Oct 2020 17:41:00

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:40:52', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5705b446-4366-4617-8d47-c9e413382276'	System	29 Oct 2020 17:41:00
User entered 'None (1)'	System	29 Oct 2020 17:41:00

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:40:56', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5705b446-4366-4617-8d47-c9e413382276'	System	29 Oct 2020 17:41:00
User entered '29 Oct 2020 12:40'	System	29 Oct 2020 17:41:00

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 3'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:32:36', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b06791cf-2e1c-4f8d-a3eb-82547b1b8cde'	System	30 Oct 2020 21:32:57
User entered 'None (1)'	System	30 Oct 2020 21:32:57

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:32:41', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b06791cf-2e1c-4f8d-a3eb-82547b1b8cde'	System	30 Oct 2020 21:32:57
User entered 'No (N)'	System	30 Oct 2020 21:32:57

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:32:44', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b06791cf-2e1c-4f8d-a3eb-82547b1b8cde'	System	30 Oct 2020 21:32:57
User entered 'No (N)'	System	30 Oct 2020 21:32:57

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:32:48', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b06791cf-2e1c-4f8d-a3eb-82547b1b8cde'	System	30 Oct 2020 21:32:57
User entered 'None (1)'	System	30 Oct 2020 21:32:57

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:32:54', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b06791cf-2e1c-4f8d-a3eb-82547b1b8cde'	System	30 Oct 2020 21:32:57
User entered '30 Oct 2020 16:32'	System	30 Oct 2020 21:32:57

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 4'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:05:50', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '211bec1c-15c2-4d1c-9b4e-dc6bc6c3b514'	System	31 Oct 2020 19:06:08
User entered 'None (1)'	System	31 Oct 2020 19:06:08

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:05:53', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '211bec1c-15c2-4d1c-9b4e-dc6bc6c3b514'	System	31 Oct 2020 19:06:08
User entered 'No (N)'	System	31 Oct 2020 19:06:08

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:05:57', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '211bec1c-15c2-4d1c-9b4e-dc6bc6c3b514'	System	31 Oct 2020 19:06:08
User entered 'No (N)'	System	31 Oct 2020 19:06:08

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:06:01', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '211bec1c-15c2-4d1c-9b4e-dc6bc6c3b514'	System	31 Oct 2020 19:06:08
User entered 'None (1)'	System	31 Oct 2020 19:06:08

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:06:05', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '211bec1c-15c2-4d1c-9b4e-dc6bc6c3b514'	System	31 Oct 2020 19:06:08
User entered '31 Oct 2020 14:06'	System	31 Oct 2020 19:06:08

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '31 Oct 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '01 Nov 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 5'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:49:02', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '4a0c7496-44ea-41fe-b1c0-fb7eb08aaa56'	System	01 Nov 2020 18:49:24
User entered 'None (1)'	System	01 Nov 2020 18:49:24

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:49:07', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '4a0c7496-44ea-41fe-b1c0-fb7eb08aaa56'	System	01 Nov 2020 18:49:24
User entered 'No (N)'	System	01 Nov 2020 18:49:24

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:49:11', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '4a0c7496-44ea-41fe-b1c0-fb7eb08aaa56'	System	01 Nov 2020 18:49:24
User entered 'No (N)'	System	01 Nov 2020 18:49:24

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:49:14', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '4a0c7496-44ea-41fe-b1c0-fb7eb08aaa56'	System	01 Nov 2020 18:49:24
User entered 'None (1)'	System	01 Nov 2020 18:49:24

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:49:19', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '4a0c7496-44ea-41fe-b1c0-fb7eb08aaa56'	System	01 Nov 2020 18:49:24
User entered '01 Nov 2020 12:49'	System	01 Nov 2020 18:49:24

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '01 Nov 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '02 Nov 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 6'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:11', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fc8af860-b6bd-484b-87a5-6a9829dc97c7'	System	02 Nov 2020 19:58:28
User entered 'None (1)'	System	02 Nov 2020 19:58:28

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:14', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fc8af860-b6bd-484b-87a5-6a9829dc97c7'	System	02 Nov 2020 19:58:28
User entered 'No (N)'	System	02 Nov 2020 19:58:28

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:17', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fc8af860-b6bd-484b-87a5-6a9829dc97c7'	System	02 Nov 2020 19:58:28
User entered 'No (N)'	System	02 Nov 2020 19:58:28

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:22', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fc8af860-b6bd-484b-87a5-6a9829dc97c7'	System	02 Nov 2020 19:58:28
User entered 'None (1)'	System	02 Nov 2020 19:58:28

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:24', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fc8af860-b6bd-484b-87a5-6a9829dc97c7'	System	02 Nov 2020 19:58:28
User entered '02 Nov 2020 13:58'	System	02 Nov 2020 19:58:28

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '02 Nov 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '03 Nov 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 7'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:29', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fa9947fc-cca9-4fc8-9fcf-13ae7f4576d3'	System	03 Nov 2020 19:06:49
User entered 'None (1)'	System	03 Nov 2020 19:06:49

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:32', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fa9947fc-cca9-4fc8-9fcf-13ae7f4576d3'	System	03 Nov 2020 19:06:49
User entered 'No (N)'	System	03 Nov 2020 19:06:49

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:35', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fa9947fc-cca9-4fc8-9fcf-13ae7f4576d3'	System	03 Nov 2020 19:06:49
User entered 'No (N)'	System	03 Nov 2020 19:06:49

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:39', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fa9947fc-cca9-4fc8-9fcf-13ae7f4576d3'	System	03 Nov 2020 19:06:49
User entered 'None (1)'	System	03 Nov 2020 19:06:49

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:46', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'fa9947fc-cca9-4fc8-9fcf-13ae7f4576d3'	System	03 Nov 2020 19:06:49
User entered '03 Nov 2020 13:06'	System	03 Nov 2020 19:06:49

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '03 Nov 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '04 Nov 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:14:02', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5dbf0c55-9d05-4aba-a858-0465e0b6a554'	System	28 Oct 2020 16:14:34
User entered 'None (0)'	System	28 Oct 2020 16:14:34

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:14:04', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5dbf0c55-9d05-4aba-a858-0465e0b6a554'	System	28 Oct 2020 16:14:34
User entered 'None (0)'	System	28 Oct 2020 16:14:34

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:14:08', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5dbf0c55-9d05-4aba-a858-0465e0b6a554'	System	28 Oct 2020 16:14:34
User entered 'None (0)'	System	28 Oct 2020 16:14:34

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:14:12', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5dbf0c55-9d05-4aba-a858-0465e0b6a554'	System	28 Oct 2020 16:14:34
User entered 'None (0)'	System	28 Oct 2020 16:14:34

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:14:15', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5dbf0c55-9d05-4aba-a858-0465e0b6a554'	System	28 Oct 2020 16:14:34
User entered 'None (0)'	System	28 Oct 2020 16:14:34

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:14:18', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5dbf0c55-9d05-4aba-a858-0465e0b6a554'	System	28 Oct 2020 16:14:34
User entered 'None (0)'	System	28 Oct 2020 16:14:34

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:14:26', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5dbf0c55-9d05-4aba-a858-0465e0b6a554'	System	28 Oct 2020 16:14:34
User entered 'No (N)'	System	28 Oct 2020 16:14:34

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-28T11:14:29', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '5dbf0c55-9d05-4aba-a858-0465e0b6a554'	System	28 Oct 2020 16:14:34
User entered '28 Oct 2020 11:14'	System	28 Oct 2020 16:14:34

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '28 Oct 2020 10:53'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '28 Oct 2020 13:23'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 1, after vaccination (at home)'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:08:21', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'be08a82e-f0ee-44bd-a011-1511643d0244'	System	29 Oct 2020 13:09:14
User entered 'None (0)'	System	29 Oct 2020 13:09:14

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:08:24', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'be08a82e-f0ee-44bd-a011-1511643d0244'	System	29 Oct 2020 13:09:14
User entered 'None (0)'	System	29 Oct 2020 13:09:14

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:08:34', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'be08a82e-f0ee-44bd-a011-1511643d0244'	System	29 Oct 2020 13:09:14
User entered 'None (0)'	System	29 Oct 2020 13:09:14

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:08:47', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'be08a82e-f0ee-44bd-a011-1511643d0244'	System	29 Oct 2020 13:09:14
User entered 'None (0)'	System	29 Oct 2020 13:09:14

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:08:51', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'be08a82e-f0ee-44bd-a011-1511643d0244'	System	29 Oct 2020 13:09:14
User entered 'None (0)'	System	29 Oct 2020 13:09:14

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:08:55', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'be08a82e-f0ee-44bd-a011-1511643d0244'	System	29 Oct 2020 13:09:14
User entered 'None (0)'	System	29 Oct 2020 13:09:14

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:09:07', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'be08a82e-f0ee-44bd-a011-1511643d0244'	System	29 Oct 2020 13:09:14
User entered 'No (N)'	System	29 Oct 2020 13:09:14

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T08:09:09', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'be08a82e-f0ee-44bd-a011-1511643d0244'	System	29 Oct 2020 13:09:14
User entered '29 Oct 2020 08:09'	System	29 Oct 2020 13:09:14

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '28 Oct 2020 14:18'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '29 Oct 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 2'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:41:01', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '92657aa2-df60-4469-9afc-1ead54a43a81'	System	29 Oct 2020 17:41:36
User entered 'None (0)'	System	29 Oct 2020 17:41:36

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:41:04', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '92657aa2-df60-4469-9afc-1ead54a43a81'	System	29 Oct 2020 17:41:36
User entered 'None (0)'	System	29 Oct 2020 17:41:36

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:41:07', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '92657aa2-df60-4469-9afc-1ead54a43a81'	System	29 Oct 2020 17:41:36
User entered 'None (0)'	System	29 Oct 2020 17:41:36

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:41:14', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '92657aa2-df60-4469-9afc-1ead54a43a81'	System	29 Oct 2020 17:41:36
User entered 'None (0)'	System	29 Oct 2020 17:41:36

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:41:18', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '92657aa2-df60-4469-9afc-1ead54a43a81'	System	29 Oct 2020 17:41:36
User entered 'None (0)'	System	29 Oct 2020 17:41:36

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:41:21', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '92657aa2-df60-4469-9afc-1ead54a43a81'	System	29 Oct 2020 17:41:36
User entered 'None (0)'	System	29 Oct 2020 17:41:36

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:41:27', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '92657aa2-df60-4469-9afc-1ead54a43a81'	System	29 Oct 2020 17:41:36
User entered 'No (N)'	System	29 Oct 2020 17:41:36

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-29T12:41:29', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '92657aa2-df60-4469-9afc-1ead54a43a81'	System	29 Oct 2020 17:41:36
User entered '29 Oct 2020 12:41'	System	29 Oct 2020 17:41:36

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '29 Oct 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Oct 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 3'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:33:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '23edeb71-7722-471e-853a-666da2a967b9'	System	30 Oct 2020 21:33:40
User entered 'None (0)'	System	30 Oct 2020 21:33:40

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:33:02', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '23edeb71-7722-471e-853a-666da2a967b9'	System	30 Oct 2020 21:33:40
User entered 'None (0)'	System	30 Oct 2020 21:33:40

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:33:06', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '23edeb71-7722-471e-853a-666da2a967b9'	System	30 Oct 2020 21:33:40
User entered 'None (0)'	System	30 Oct 2020 21:33:40

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:33:09', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '23edeb71-7722-471e-853a-666da2a967b9'	System	30 Oct 2020 21:33:40
User entered 'None (0)'	System	30 Oct 2020 21:33:40

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:33:20', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '23edeb71-7722-471e-853a-666da2a967b9'	System	30 Oct 2020 21:33:40
User entered 'None (0)'	System	30 Oct 2020 21:33:40

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:33:23', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '23edeb71-7722-471e-853a-666da2a967b9'	System	30 Oct 2020 21:33:40
User entered 'None (0)'	System	30 Oct 2020 21:33:40

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:33:31', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '23edeb71-7722-471e-853a-666da2a967b9'	System	30 Oct 2020 21:33:40
User entered 'No (N)'	System	30 Oct 2020 21:33:40

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-30T16:33:34', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '23edeb71-7722-471e-853a-666da2a967b9'	System	30 Oct 2020 21:33:40
User entered '30 Oct 2020 16:33'	System	30 Oct 2020 21:33:40

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 4'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:06:21', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e2109358-455e-4342-9b88-d9bea7f5aa52'	System	31 Oct 2020 19:07:01
User entered 'None (0)'	System	31 Oct 2020 19:07:01

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:06:23', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e2109358-455e-4342-9b88-d9bea7f5aa52'	System	31 Oct 2020 19:07:01
User entered 'None (0)'	System	31 Oct 2020 19:07:01

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:06:32', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e2109358-455e-4342-9b88-d9bea7f5aa52'	System	31 Oct 2020 19:07:01
User entered 'None (0)'	System	31 Oct 2020 19:07:01

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:06:43', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e2109358-455e-4342-9b88-d9bea7f5aa52'	System	31 Oct 2020 19:07:01
User entered 'No interference with activity (1)'	System	31 Oct 2020 19:07:01

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:06:48', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e2109358-455e-4342-9b88-d9bea7f5aa52'	System	31 Oct 2020 19:07:01
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	31 Oct 2020 19:07:01

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:06:50', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e2109358-455e-4342-9b88-d9bea7f5aa52'	System	31 Oct 2020 19:07:01
User entered 'None (0)'	System	31 Oct 2020 19:07:01

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:06:55', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e2109358-455e-4342-9b88-d9bea7f5aa52'	System	31 Oct 2020 19:07:01
User entered 'No (N)'	System	31 Oct 2020 19:07:01

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-10-31T14:06:58', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e2109358-455e-4342-9b88-d9bea7f5aa52'	System	31 Oct 2020 19:07:01
User entered '31 Oct 2020 14:06'	System	31 Oct 2020 19:07:01

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '31 Oct 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '01 Nov 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 5'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:49:26', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b6aba20a-178b-46ed-9033-85e8b3c8ff5f'	System	01 Nov 2020 18:50:15
User entered 'None (0)'	System	01 Nov 2020 18:50:15

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:49:29', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b6aba20a-178b-46ed-9033-85e8b3c8ff5f'	System	01 Nov 2020 18:50:15
User entered 'None (0)'	System	01 Nov 2020 18:50:15

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:49:34', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b6aba20a-178b-46ed-9033-85e8b3c8ff5f'	System	01 Nov 2020 18:50:15
User entered 'None (0)'	System	01 Nov 2020 18:50:15

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:49:38', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b6aba20a-178b-46ed-9033-85e8b3c8ff5f'	System	01 Nov 2020 18:50:15
User entered 'None (0)'	System	01 Nov 2020 18:50:15

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:50:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b6aba20a-178b-46ed-9033-85e8b3c8ff5f'	System	01 Nov 2020 18:50:15
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	01 Nov 2020 18:50:15

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:50:04', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b6aba20a-178b-46ed-9033-85e8b3c8ff5f'	System	01 Nov 2020 18:50:15
User entered 'None (0)'	System	01 Nov 2020 18:50:15

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:50:11', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b6aba20a-178b-46ed-9033-85e8b3c8ff5f'	System	01 Nov 2020 18:50:15
User entered 'No (N)'	System	01 Nov 2020 18:50:15

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-01T12:50:13', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b6aba20a-178b-46ed-9033-85e8b3c8ff5f'	System	01 Nov 2020 18:50:15
User entered '01 Nov 2020 12:50'	System	01 Nov 2020 18:50:15

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '01 Nov 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '02 Nov 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 6'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:28', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '7df3ee41-b2d1-4d30-8044-40f5505ea214'	System	02 Nov 2020 19:58:53
User entered 'None (0)'	System	02 Nov 2020 19:58:53

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:32', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '7df3ee41-b2d1-4d30-8044-40f5505ea214'	System	02 Nov 2020 19:58:53
User entered 'None (0)'	System	02 Nov 2020 19:58:53

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:35', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '7df3ee41-b2d1-4d30-8044-40f5505ea214'	System	02 Nov 2020 19:58:53
User entered 'None (0)'	System	02 Nov 2020 19:58:53

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:38', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '7df3ee41-b2d1-4d30-8044-40f5505ea214'	System	02 Nov 2020 19:58:53
User entered 'None (0)'	System	02 Nov 2020 19:58:53

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:41', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '7df3ee41-b2d1-4d30-8044-40f5505ea214'	System	02 Nov 2020 19:58:53
User entered 'None (0)'	System	02 Nov 2020 19:58:53

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:44', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '7df3ee41-b2d1-4d30-8044-40f5505ea214'	System	02 Nov 2020 19:58:53
User entered 'None (0)'	System	02 Nov 2020 19:58:53

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:48', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '7df3ee41-b2d1-4d30-8044-40f5505ea214'	System	02 Nov 2020 19:58:53
User entered 'No (N)'	System	02 Nov 2020 19:58:53

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-02T13:58:51', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '7df3ee41-b2d1-4d30-8044-40f5505ea214'	System	02 Nov 2020 19:58:53
User entered '02 Nov 2020 13:58'	System	02 Nov 2020 19:58:53

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '02 Nov 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '03 Nov 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
Data entry locked.	System	28 Oct 2020 15:37:21
User entered 'Day 7'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:51', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '986d40d9-a1fa-4b49-9940-b21b1d3ec7ba'	System	03 Nov 2020 19:07:12
User entered 'None (0)'	System	03 Nov 2020 19:07:12

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:52', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '986d40d9-a1fa-4b49-9940-b21b1d3ec7ba'	System	03 Nov 2020 19:07:12
User entered 'None (0)'	System	03 Nov 2020 19:07:12

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:55', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '986d40d9-a1fa-4b49-9940-b21b1d3ec7ba'	System	03 Nov 2020 19:07:12
User entered 'None (0)'	System	03 Nov 2020 19:07:12

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:06:57', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '986d40d9-a1fa-4b49-9940-b21b1d3ec7ba'	System	03 Nov 2020 19:07:12
User entered 'None (0)'	System	03 Nov 2020 19:07:12

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:07:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '986d40d9-a1fa-4b49-9940-b21b1d3ec7ba'	System	03 Nov 2020 19:07:12
User entered 'None (0)'	System	03 Nov 2020 19:07:12

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:07:02', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '986d40d9-a1fa-4b49-9940-b21b1d3ec7ba'	System	03 Nov 2020 19:07:12
User entered 'None (0)'	System	03 Nov 2020 19:07:12

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:07:07', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '986d40d9-a1fa-4b49-9940-b21b1d3ec7ba'	System	03 Nov 2020 19:07:12
User entered 'No (N)'	System	03 Nov 2020 19:07:12

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-03T13:07:09', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '986d40d9-a1fa-4b49-9940-b21b1d3ec7ba'	System	03 Nov 2020 19:07:12
User entered '03 Nov 2020 13:07'	System	03 Nov 2020 19:07:12

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '03 Nov 2020 12:00'	System	28 Oct 2020 15:37:21

US3492273

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:02:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:01:16
User entered '04 Nov 2020 11:59'	System	28 Oct 2020 15:37:21

US3492273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 14:59:54

US3492273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:04
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 14:59:54

US3492273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Nov 2020 14:59:54

US3492273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:04
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:59:54

US3492273

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:14:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:00:05

US3492273

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'I'	System	05 Nov 2020 15:00:05

US3492273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 23:28:26

US3492273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:15
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 23:28:26

US3492273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Nov 2020 23:28:26

US3492273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:15
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 23:28:26

US3492273

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 23:29:09

US3492273

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'I'	System	11 Nov 2020 23:29:09

US3492273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:38
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:48:42

US3492273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:38
User entered '18 Nov 2020'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:48:42

US3492273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:38
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:48:42

US3492273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:38
User entered empty.	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:48:42

US3492273

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:41
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:48:30

US3492273

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'I'	System	19 Nov 2020 14:48:30

US3492273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 13:59:40

US3492273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:43
User entered '25 Nov 2020'	(b) (4), (b) (6)	07 Dec 2020 13:59:40

US3492273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Dec 2020 13:59:40

US3492273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User entered 'VISIT3'	System	07 Dec 2020 13:59:40

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:46
User entered '25 Nov 2020'	(b) (4), (b) (6)	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:46
User entered '08:08'	(b) (4), (b) (6)	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User entered '25 Nov 2020 08:08'	System	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:46
User entered '97.4' F	(b) (4), (b) (6)	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:46
User entered 'Other (Other)'	(b) (4), (b) (6)	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:46
User entered 'tympanic'	(b) (4), (b) (6)	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:46
User entered '70'	(b) (4), (b) (6)	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User entered 'bpm'	System	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:46
User entered '20'	(b) (4), (b) (6)	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User entered 'breaths/min'	System	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:46
User entered '125'	(b) (4), (b) (6)	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User entered 'mmHg'	System	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:46
User entered '80'	(b) (4), (b) (6)	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User entered 'mmHg'	System	07 Dec 2020 14:00:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16

US3492273

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 14:00:25

US3492273

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:48
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 14:00:25

US3492273

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 14:01:42

US3492273

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:50
User entered '25 Nov 2020'	(b) (4), (b) (6)	07 Dec 2020 14:01:42

US3492273

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:50
User entered '08:25'	(b) (4), (b) (6)	07 Dec 2020 14:01:42

US3492273

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:59:16
User entered '25 Nov 2020 08:25'	System	07 Dec 2020 14:01:42

US3492273

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 20:39:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 14:01:50

US3492273

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'I'	System	07 Dec 2020 14:01:50

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2020-11-27T07:46:24', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0d05549f-5455-40c9-a4e4-d52b865a222a'	System	27 Nov 2020 13:46:48
User entered 'No (N)'	System	27 Nov 2020 13:46:48

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2020-11-27T07:46:39', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0d05549f-5455-40c9-a4e4-d52b865a222a'	System	27 Nov 2020 13:46:48
User entered 'No (N)'	System	27 Nov 2020 13:46:48

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-11-27T07:46:45', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0d05549f-5455-40c9-a4e4-d52b865a222a'	System	27 Nov 2020 13:46:48
User entered '27 Nov 2020 07:46:45'	System	27 Nov 2020 13:46:48

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2020-12-04T08:03:34', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '6457b370-d943-407e-8dc6-01751d0957c9'	System	04 Dec 2020 14:03:51
User entered 'No (N)'	System	04 Dec 2020 14:03:51

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2020-12-04T08:03:42', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '6457b370-d943-407e-8dc6-01751d0957c9'	System	04 Dec 2020 14:03:51
User entered 'No (N)'	System	04 Dec 2020 14:03:51

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-12-04T08:03:46', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '6457b370-d943-407e-8dc6-01751d0957c9'	System	04 Dec 2020 14:03:51
User entered '04 Dec 2020 08:03:46'	System	04 Dec 2020 14:03:51

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2020-12-11T09:29:56', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'f057d2ad-af25-4a11-9aac-083cf2f25c7f'	System	11 Dec 2020 15:30:13
User entered 'No (N)'	System	11 Dec 2020 15:30:13

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2020-12-11T09:30:02', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'f057d2ad-af25-4a11-9aac-083cf2f25c7f'	System	11 Dec 2020 15:30:13
User entered 'No (N)'	System	11 Dec 2020 15:30:13

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-12-11T09:30:07', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'f057d2ad-af25-4a11-9aac-083cf2f25c7f' User entered '11 Dec 2020 09:30:07'	System	11 Dec 2020 15:30:13
	System	11 Dec 2020 15:30:13

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2020-12-18T06:18:58', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd1ce51f8-5a1b-46c3-939e-7e7b976f6917'	System	18 Dec 2020 12:19:39
User entered 'No (N)'	System	18 Dec 2020 12:19:39

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2020-12-18T06:19:12', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd1ce51f8-5a1b-46c3-939e-7e7b976f6917'	System	18 Dec 2020 12:19:39
User entered 'No (N)'	System	18 Dec 2020 12:19:39

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-12-18T06:19:18', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd1ce51f8-5a1b-46c3-939e-7e7b976f6917'	System	18 Dec 2020 12:19:39
User entered '18 Dec 2020 06:19:18'	System	18 Dec 2020 12:19:39

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2020-12-25T05:03:17', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e06c17ea-1c51-440f-b5df-1e4625db96b2'	System	25 Dec 2020 11:03:36
User entered 'No (N)'	System	25 Dec 2020 11:03:36

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2020-12-25T05:03:26', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e06c17ea-1c51-440f-b5df-1e4625db96b2'	System	25 Dec 2020 11:03:36
User entered 'No (N)'	System	25 Dec 2020 11:03:36

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2020-12-25T05:03:32', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'e06c17ea-1c51-440f-b5df-1e4625db96b2'	System	25 Dec 2020 11:03:36
User entered '25 Dec 2020 05:03:32'	System	25 Dec 2020 11:03:36

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-01-04T12:03:02', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'dba89056-0112-476d-a27d-363560376dc5'	System	04 Jan 2021 18:04:15
User entered 'Yes (Y)'	System	04 Jan 2021 18:04:15

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-01-04T12:03:08', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'dba89056-0112-476d-a27d-363560376dc5'	System	04 Jan 2021 18:04:15
User entered 'No (N)'	System	04 Jan 2021 18:04:15

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-01-04T12:03:16', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'dba89056-0112-476d-a27d-363560376dc5'	System	04 Jan 2021 18:04:15
User entered 'No (N)'	System	04 Jan 2021 18:04:15

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-01-04T12:03:25', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'dba89056-0112-476d-a27d-363560376dc5'	System	04 Jan 2021 18:04:15
User entered 'Yes (Y)'	System	04 Jan 2021 18:04:15

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-01-04T12:03:42', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'dba89056-0112-476d-a27d-363560376dc5'	System	04 Jan 2021 18:04:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Jan 2021 18:04:15

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-01-04T12:04:03', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'dba89056-0112-476d-a27d-363560376dc5'	System	04 Jan 2021 18:04:15
User entered '04 Jan 2021 12:04:03'	System	04 Jan 2021 18:04:15

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-01-08T07:55:58', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0807a44d-8ab8-4696-ab89-406b29c6f166'	System	08 Jan 2021 13:56:11
User entered 'No (N)'	System	08 Jan 2021 13:56:11

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-01-08T07:56:03', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0807a44d-8ab8-4696-ab89-406b29c6f166'	System	08 Jan 2021 13:56:11
User entered 'No (N)'	System	08 Jan 2021 13:56:11

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-01-08T07:56:08', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '0807a44d-8ab8-4696-ab89-406b29c6f166'	System	08 Jan 2021 13:56:11
User entered '08 Jan 2021 07:56:08'	System	08 Jan 2021 13:56:11

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-01-15T07:32:41', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd813733c-882f-4c0e-a0b8-9252f0ccb713'	System	15 Jan 2021 13:32:53
User entered 'No (N)'	System	15 Jan 2021 13:32:53

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-01-15T07:32:46', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd813733c-882f-4c0e-a0b8-9252f0ccb713'	System	15 Jan 2021 13:32:53
User entered 'No (N)'	System	15 Jan 2021 13:32:53

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-01-15T07:32:50', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd813733c-882f-4c0e-a0b8-9252f0ccb713'	System	15 Jan 2021 13:32:53
User entered '15 Jan 2021 07:32:50'	System	15 Jan 2021 13:32:53

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-01-22T17:30:18', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '71e6f416-f8d7-4704-8c94-41c90fb5a7ad'	System	22 Jan 2021 23:30:31
User entered 'No (N)'	System	22 Jan 2021 23:30:31

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-01-22T17:30:25', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '71e6f416-f8d7-4704-8c94-41c90fb5a7ad'	System	22 Jan 2021 23:30:31
User entered 'No (N)'	System	22 Jan 2021 23:30:31

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-01-22T17:30:28', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '71e6f416-f8d7-4704-8c94-41c90fb5a7ad'	System	22 Jan 2021 23:30:31
User entered '22 Jan 2021 17:30:28'	System	22 Jan 2021 23:30:31

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-01-29T04:30:12', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '47e18ea6-89a9-4945-b61e-6570b8cca61b'	System	29 Jan 2021 10:30:27
User entered 'No (N)'	System	29 Jan 2021 10:30:27

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-01-29T04:30:22', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '47e18ea6-89a9-4945-b61e-6570b8cca61b'	System	29 Jan 2021 10:30:27
User entered 'No (N)'	System	29 Jan 2021 10:30:27

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-01-29T04:30:25', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '47e18ea6-89a9-4945-b61e-6570b8cca61b'	System	29 Jan 2021 10:30:27
User entered '29 Jan 2021 04:30:25'	System	29 Jan 2021 10:30:27

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-02-05T10:10:15', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '33e3ebd9-f9b8-4c58-b0d1-593b4cce4142'	System	05 Feb 2021 16:11:04
User entered 'Yes (Y)'	System	05 Feb 2021 16:11:04

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-02-05T10:10:22', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '33e3ebd9-f9b8-4c58-b0d1-593b4cce4142'	System	05 Feb 2021 16:11:04
User entered 'No (N)'	System	05 Feb 2021 16:11:04

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-02-05T10:10:28', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '33e3ebd9-f9b8-4c58-b0d1-593b4cce4142'	System	05 Feb 2021 16:11:04
User entered 'No (N)'	System	05 Feb 2021 16:11:04

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-02-05T10:10:43', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '33e3ebd9-f9b8-4c58-b0d1-593b4cce4142'	System	05 Feb 2021 16:11:04
User entered 'Yes (Y)'	System	05 Feb 2021 16:11:04

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-02-05T10:10:52', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '33e3ebd9-f9b8-4c58-b0d1-593b4cce4142'	System	05 Feb 2021 16:11:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Feb 2021 16:11:04

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-02-05T10:10:55', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '33e3ebd9-f9b8-4c58-b0d1-593b4cce4142'	System	05 Feb 2021 16:11:04
User entered '05 Feb 2021 10:10:55'	System	05 Feb 2021 16:11:04

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-02-12T04:20:33', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'edeeadc7-4365-40f3-a140-9e48185f0142'	System	12 Feb 2021 10:20:45
User entered 'No (N)'	System	12 Feb 2021 10:20:45

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-02-12T04:20:38', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'edeeadc7-4365-40f3-a140-9e48185f0142'	System	12 Feb 2021 10:20:45
User entered 'No (N)'	System	12 Feb 2021 10:20:45

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-02-12T04:20:42', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'edeeadc7-4365-40f3-a140-9e48185f0142'	System	12 Feb 2021 10:20:45
User entered '12 Feb 2021 04:20:42'	System	12 Feb 2021 10:20:45

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-02-19T06:02:47', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '1a5ccf85-c625-4969-b2b7-6b29c948e720'	System	19 Feb 2021 12:03:03
User entered 'No (N)'	System	19 Feb 2021 12:03:03

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-02-19T06:02:52', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '1a5ccf85-c625-4969-b2b7-6b29c948e720'	System	19 Feb 2021 12:03:03
User entered 'No (N)'	System	19 Feb 2021 12:03:03

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-02-19T06:03:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '1a5ccf85-c625-4969-b2b7-6b29c948e720'	System	19 Feb 2021 12:03:03
User entered '19 Feb 2021 06:03:00'	System	19 Feb 2021 12:03:03

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-03-01T14:04:37-06:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '39b5be8f-2eba-4b6f-aaeb-4e6afbadb44f' User entered 'No (N)'	System	01 Mar 2021 20:05:28
	System	01 Mar 2021 20:05:28

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-03-01T14:04:42-06:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '39b5be8f-2eba-4b6f-aaeb-4e6afbadb44f'	System	01 Mar 2021 20:05:28
User entered 'No (N)'	System	01 Mar 2021 20:05:28

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-03-01T14:04:45-06:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '39b5be8f-2eba-4b6f-aaeb-4e6afbadb44f' User entered '01 Mar 2021 14:04:45'	System	01 Mar 2021 20:05:28
	System	01 Mar 2021 20:05:28

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-03-05T04:18:17-06:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'eeca5722-cab5-4e1b-a1d3-e8efbeda15f8'	System	05 Mar 2021 10:18:28
User entered 'No (N)'	System	05 Mar 2021 10:18:28

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-03-05T04:18:22-06:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'eeca5722-cab5-4e1b-a1d3-e8efbeda15f8'	System	05 Mar 2021 10:18:28
User entered 'No (N)'	System	05 Mar 2021 10:18:28

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-03-05T04:18:25-06:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'eeca5722-cab5-4e1b-a1d3-e8efbeda15f8' User entered '05 Mar 2021 04:18:25'	System	05 Mar 2021 10:18:28
	System	05 Mar 2021 10:18:28

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-03-12T05:52:17-06:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '900a15e1-3dff-4839-aac5-e73ea9fdda13'	System	12 Mar 2021 11:52:30
User entered 'No (N)'	System	12 Mar 2021 11:52:30

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-03-12T05:52:22-06:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '900a15e1-3dff-4839-aac5-e73ea9fdda13'	System	12 Mar 2021 11:52:30
User entered 'No (N)'	System	12 Mar 2021 11:52:30

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-03-12T05:52:26-06:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '900a15e1-3dff-4839-aac5-e73ea9fdda13' User entered '12 Mar 2021 05:52:26'	System	12 Mar 2021 11:52:30
	System	12 Mar 2021 11:52:30

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-03-19T06:38:08-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd147055d-7707-4264-9a39-12fe65fd3ebb' User entered 'No (N)'	System	19 Mar 2021 11:38:20
	System	19 Mar 2021 11:38:20

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-03-19T06:38:12-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd147055d-7707-4264-9a39-12fe65fd3ebb' User entered 'No (N)'	System	19 Mar 2021 11:38:20
	System	19 Mar 2021 11:38:20

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-03-19T06:38:15-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'd147055d-7707-4264-9a39-12fe65fd3ebb' User entered '19 Mar 2021 06:38:15'	System	19 Mar 2021 11:38:20
	System	19 Mar 2021 11:38:20

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-03-26T06:07:35-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '2e13d90f-92f8-4456-bc12-0b8cac3ee8ef' User entered 'No (N)'	System	26 Mar 2021 11:07:49
	System	26 Mar 2021 11:07:49

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-03-26T06:07:41-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '2e13d90f-92f8-4456-bc12-0b8cac3ee8ef'	System	26 Mar 2021 11:07:49
User entered 'No (N)'	System	26 Mar 2021 11:07:49

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-03-26T06:07:46-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '2e13d90f-92f8-4456-bc12-0b8cac3ee8ef' User entered '26 Mar 2021 06:07:46'	System	26 Mar 2021 11:07:49
	System	26 Mar 2021 11:07:49

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-04-06T15:16:30-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '260564cd-db2c-4755-8b6b-83ba03461c00'	System	06 Apr 2021 20:16:39
User entered 'No (N)'	System	06 Apr 2021 20:16:39

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-04-06T15:16:33-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '260564cd-db2c-4755-8b6b-83ba03461c00'	System	06 Apr 2021 20:16:39
User entered 'No (N)'	System	06 Apr 2021 20:16:39

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-04-06T15:16:35-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '260564cd-db2c-4755-8b6b-83ba03461c00'	System	06 Apr 2021 20:16:39
User entered '06 Apr 2021 15:16:35'	System	06 Apr 2021 20:16:39

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-04-09T04:11:06-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'c0dac5be-de45-46f6-a891-3dbe3257d89c' User entered 'No (N)'	System	09 Apr 2021 09:11:38
	System	09 Apr 2021 09:11:38

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-04-09T04:11:09-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'c0dac5be-de45-46f6-a891-3dbe3257d89c'	System	09 Apr 2021 09:11:38
User entered 'No (N)'	System	09 Apr 2021 09:11:38

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-04-09T04:11:12-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'c0dac5be-de45-46f6-a891-3dbe3257d89c' User entered '09 Apr 2021 04:11:12'	System	09 Apr 2021 09:11:38
	System	09 Apr 2021 09:11:38

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-04-16T05:00:30-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '19921209-ef0b-4732-b83a-f25f94a7ca46'	System	16 Apr 2021 10:00:41
User entered 'No (N)'	System	16 Apr 2021 10:00:41

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-04-16T05:00:35-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '19921209-ef0b-4732-b83a-f25f94a7ca46'	System	16 Apr 2021 10:00:41
User entered 'No (N)'	System	16 Apr 2021 10:00:41

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-04-16T05:00:38-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '19921209-ef0b-4732-b83a-f25f94a7ca46'	System	16 Apr 2021 10:00:41
User entered '16 Apr 2021 05:00:38'	System	16 Apr 2021 10:00:41

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-04-23T05:52:33-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '85fedfd9-b7db-44e3-8951-1851cf0c5b00'	System	23 Apr 2021 10:52:43
User entered 'No (N)'	System	23 Apr 2021 10:52:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-04-23T05:52:35-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '85fedfd9-b7db-44e3-8951-1851cf0c5b00'	System	23 Apr 2021 10:52:43
User entered 'No (N)'	System	23 Apr 2021 10:52:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-04-23T05:52:38-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: '85fedfd9-b7db-44e3-8951-1851cf0c5b00'	System	23 Apr 2021 10:52:43
User entered '23 Apr 2021 05:52:38'	System	23 Apr 2021 10:52:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[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 (9ec5ff1def3955c7)', Time: '2021-04-30T12:36:08-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b096e64c-1099-4844-8125-3555509c75de' User entered 'No (N)'	System	30 Apr 2021 17:36:23
	System	30 Apr 2021 17:36:23

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

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 (9ec5ff1def3955c7)', Time: '2021-04-30T12:36:13-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b096e64c-1099-4844-8125-3555509c75de'	System	30 Apr 2021 17:36:23
User entered 'No (N)'	System	30 Apr 2021 17:36:23

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-04-30T12:36:16-05:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'b096e64c-1099-4844-8125-3555509c75de' User entered '30 Apr 2021 12:36:16'	System	30 Apr 2021 17:36:23
	System	30 Apr 2021 17:36:23

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 11:18:43

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 11:18:43

US3492273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:02:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:18:43
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 11:18:43

US3492273

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:02:29

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)	24 Apr 2021 13:32:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-03-01T14:04:09-06:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'be385fb6-cc63-427b-bdba-5a2303c8ba9b'	System	01 Mar 2021 20:05:22
User entered 'No (N)'	System	01 Mar 2021 20:05:22

US3492273

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:02:29

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:32:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9ec5ff1def3955c7)', Time: '2021-03-01T14:04:26-06:00', User OID: 'PatientReportedOutcome (US3492273)', ODM File OID: 'be385fb6-cc63-427b-bdba-5a2303c8ba9b'	System	01 Mar 2021 20:05:22
User entered '01 Mar 2021 14:04:26'	System	01 Mar 2021 20:05:22

US3492273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:53:38
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:37:50

US3492273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:53:38
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '21 Dec 2020'	Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:37:50

US3492273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:53:38
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:37:50

US3492273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:53:38
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:37:50

US3492273

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:53:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:37:53

US3492273

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:58:56
User entered 'I'	System	21 Dec 2020 16:37:53

US3492273

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	Ian Feather (b) (4)	25 Jan 2021 15:53:13

US3492273

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '25 Jan 2021'	Ian Feather (b) (4)	25 Jan 2021 15:53:13

US3492273

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	25 Jan 2021 15:53:13

US3492273

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) Ian Feather (b) (4) (b) (4)	25 Jan 2021 15:53:13

US3492273

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	Ian Feather (b) (4)	25 Jan 2021 15:53:19

US3492273

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
User entered 'I'	System	25 Jan 2021 15:53:19

US3492273

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:29
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 16:33:48

US3492273

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:29
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered '23 Feb 2021'	(b) (4) Nia Moragne-O'Neal (b) (4)	23 Feb 2021 16:33:48

US3492273

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:29
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 16:33:48

US3492273

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:29
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered empty.	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 16:33:48

US3492273

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:33
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 16:35:50

US3492273

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
User entered 'I'	System	23 Feb 2021 16:35:50

US3492273

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:38
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered 'Yes (Y)'	Ian Feather (b) (4)	24 Mar 2021 14:26:08

US3492273

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:38
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered '24 Mar 2021'	(b) (4) Ian Feather (b) (4) (b) (4)	24 Mar 2021 14:26:08

US3492273

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:38
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4)	24 Mar 2021 14:26:08

US3492273

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:02:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:38
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered empty.	(b) (4) Ian Feather (b) (4) (b) (4)	24 Mar 2021 14:26:08

US3492273

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:35:42
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered 'Yes (Y)'	Ian Feather (b) (4)	24 Mar 2021 14:26:12

US3492273

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:21:53
User entered 'I'	System	24 Mar 2021 14:26:12

US3492273

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:47:34

US3492273

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User entered '26 Apr 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:47:34

US3492273

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:47:34

US3492273

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	26 Apr 2021 15:47:34

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:20
User entered '26 Apr 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:20
User entered '08:10'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '26 Apr 2021 08:10'	System	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:20
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:20
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:20
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	(b) (4) System	26 Apr 2021 18:08:41
User entered 'tympanic' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	26 Apr 2021 18:08:41
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	26 Apr 2021 15:51:36
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:20
User entered '62'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:20
User entered '18'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:20
User entered '125'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	28 Apr 2021 03:53:20
User entered '76'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:02:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Apr 2021 15:51:36

US3492273

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:38

US3492273

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:02:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:38

US3492273

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:53

US3492273

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User entered '26 Apr 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:53

US3492273

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User entered '08:20'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:53

US3492273

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '26 Apr 2021 08:20'	System	26 Apr 2021 15:51:53

US3492273

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:51:57

US3492273

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:02:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 15:51:57

US3492273

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

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 15:18:44

US3492273

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

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 15:18:44

US3492273

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

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[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 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:20
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Jan 2021 15:18:44

US3492273

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

Form: Visit Date

Generated On: 10 Jun 2021 08:02:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 15:18:44

US3492273

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:29

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:19:18

US3492273

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:29

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:09:56

US3492273

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 15:19:18

US3492273

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:09:56

US3492273

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:29

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:19:18

US3492273

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	19 Jan 2021 15:19:18

US3492273

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 15:43:51
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	19 Jan 2021 15:19:18

US3492273

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 15:43:51
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	19 Jan 2021 15:19:18

US3492273

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4), (b) (6)	19 Jan 2021 15:19:18

US3492273

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
User entered empty.	System	19 Jan 2021 15:19:18

US3492273

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

Form: Unblinding

Generated On: 10 Jun 2021 08:02:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
User entered empty.	System	19 Jan 2021 15:19:18

US3492273

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:27
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 15:19:53

US3492273

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:27
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 15:19:53

US3492273

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:27
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '09:03'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:19:53

US3492273

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
User entered '19 Jan 2021 09:03'	System	19 Jan 2021 15:19:53

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:02:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 15:20:12

US3492273

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 15:20:12

US3492273

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:08:30
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '08:59'	(b) (4), (b) (6)	19 Jan 2021 15:20:12

US3492273

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:27:44
User entered '19 Jan 2021 08:59'	System	19 Jan 2021 15:20:12

US3492273

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:27
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:11:54
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	07 Oct 2020 22:54:22
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:23:03

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of LEFT SHOULDER ROTATOR TEAR. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 15:54:52
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Post-traumatic pain, LLT: Post-traumatic pain - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 12:28:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	17 Nov 2020 12:28:45
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of LEFT SHOULDER ROTATOR TEAR. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 18:57:15
Data point term sent to Coder	System	16 Nov 2020 18:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 18:36:21
Coding entries removed.	(b) (4), (b) (6)	16 Nov 2020 18:36:21
User entered 'SHOULDER PAIN from car accident' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Nov 2020 18:36:21
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of LEFT SHOULDER ROTATOR TEAR. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 10:11:19
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:21:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:21:40
Data point term sent to Coder	System	08 Oct 2020 16:11:40
User closed query 'DM-Coding: Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) SHOULDER PAIN post-traumatic 2) CAR ACCIDENT etc.' (Site from System).	System	08 Oct 2020 16:11:23
Query 'DM-Coding: Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) SHOULDER PAIN post-traumatic 2) CAR ACCIDENT etc.' answered with 'updated' (Site from System).	Lorna Sanchez McCann (b) (4)	08 Oct 2020 16:11:23
User entered 'SHOULDER PAIN' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	08 Oct 2020 16:11:15
User opened query 'DM-Coding: Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) SHOULDER PAIN post-traumatic 2) CAR ACCIDENT etc.' (Site from System).	Coder Import (b) (4) (b) (4)	08 Oct 2020 10:03:18
Data point term sent to Coder	System	07 Oct 2020 22:55:58
User entered 'Shoulder pain from car accident'	(b) (4), (b) (6) (b) (4)	07 Oct 2020 22:55:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered '6 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
User entered empty.	System	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
User entered empty.	System	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered 'None (NONE)'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered 'l'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4) (b) (4), (b) (6)	04 Apr 2021 03:02:17
User closed query 'Per DM CLR: SAE Narrative = PAIN FROM CAR ACCIDENT. However, please confirm if "CAR ACCIDENT" should be recorded as a separate Adverse Event. If yes, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 15:54:50
Query 'Per DM CLR: SAE Narrative = PAIN FROM CAR ACCIDENT. However, please confirm if "CAR ACCIDENT" should be recorded as a separate Adverse Event. If yes, ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 18:58:37
User opened query 'Per DM CLR: SAE Narrative = PAIN FROM CAR ACCIDENT. However, please confirm if "CAR ACCIDENT" should be recorded as a separate Adverse Event. If yes, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 10:11:10
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:11:58
User entered 'Pain FROM CAR ACCIDENT' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	08 Oct 2020 16:11:15
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
User entered '0'	System	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17
User entered '1'	System	07 Oct 2020 22:55:25

US3492273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:17

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4) (b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 18:58:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 18:58:45
Data point term sent to Coder	System	16 Nov 2020 18:57:38
User entered 'car accident'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '06 Oct 2020'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:56:55

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
User entered empty.	System	16 Nov 2020 18:56:55

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '06 Oct 2020'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:56:55

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
User entered empty.	System	16 Nov 2020 18:56:55

US3492273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'None (NONE)'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'l'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:27
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'participant had shoulder pain and visited the doctor'	(b) (4), (b) (6)	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
User entered '0'	System	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27
User entered '1'	System	16 Nov 2020 18:56:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4) (b) (4), (b) (6)	04 Apr 2021 03:02:33
User closed query 'For coding purposes, please split INCREASED NOCTURNAL FREQUENCY AND URGENCY into separate entries. 1. INCREASED NOCTURNAL FREQUENCY and 2. INCREASED NOCTURNAL URGENCY or provide ONE diagnosis.' (Site from Coder).	(b) (4), (b) (6)	14 Mar 2021 20:21:52
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary tract signs and symptoms NEC, PT: Nocturia, LLT: Nocturnal frequency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 18:46:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 18:46:02
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User closed query 'Per DM CLR: Please review and update to reflect a medical condition or diagnosis. Was this NOCTURNAL URINARY FREQUENCY? Update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 12:21:38
Data point term sent to Coder	System	01 Mar 2021 14:29:49
Query 'Per DM CLR: Please review and update to reflect a medical condition or diagnosis. Was this NOCTURNAL URINARY FREQUENCY? Update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 14:29:08
Coding entries removed.	(b) (4), (b) (6)	01 Mar 2021 14:29:03
User entered 'INCREASED NOCTURNAL urinary FREQUENCY' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Mar 2021 14:29:03
User opened query 'Per DM CLR: Please review and update to reflect a medical condition or diagnosis. Was this NOCTURNAL URINARY FREQUENCY? Update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:57:49

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary tract signs and symptoms NEC, PT: Nocturia, LLT: Nocturnal frequency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 13:01:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 13:01:54
Data point term sent to Coder	System	02 Dec 2020 18:21:39
DataPoint Un-verified.	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:20:41
Coding entries removed.	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:20:41
User entered 'INCREASED NOCTURNAL FREQUENCY' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:20:41
Query 'For coding purposes, please split INCREASED NOCTURNAL FREQUENCY AND URGENCY into separate entries. 1. INCREASED NOCTURNAL FREQUENCY and 2. INCREASED NOCTURNAL URGENCY or provide ONE diagnosis.' answered with 'updated: condition split into two terms' (Site from Coder).	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:20:22
User opened query 'For coding purposes, please split INCREASED NOCTURNAL FREQUENCY AND URGENCY into separate entries. 1. INCREASED NOCTURNAL FREQUENCY and 2. INCREASED NOCTURNAL URGENCY or provide ONE diagnosis.' (Site from Coder).	(b) (4), (b) (6)	01 Dec 2020 13:36:57
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Pollakiuria, LLT: Urinary frequency aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:40:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:40:09
Data point term sent to Coder	System	23 Nov 2020 20:51:00
Query 'CDM Coding, please add to the text a unifying diagnosis. Alternatively split into separate records, as 'INCREASED NOCTURNAL FREQUENCY' and 'URINARY URGENCY, reporting each event with all relevant information e.g. start and stop dates etc.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:50:59

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding, please add to the text a unifying diagnosis. Alternatively split into separate records, as 'INCREASED NOCTURNAL FREQUENCY' and 'URINARY URGENCY, reporting each event with all relevant information e.g. start and stop dates etc.' (Site from System). DataPoint Verified.	Coder Import (b) (4) (b) (4)	20 Nov 2020 05:50:53
	(b) (4), (b) (6)	19 Nov 2020 18:13:41
Data point term sent to Coder	System	19 Nov 2020 14:54:44
User entered 'Increased nocturnal frequency and urgency'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:54:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'No (N)'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'No (N)'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'No (N)'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '13 Nov 2020'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:33
User entered empty.	System	19 Nov 2020 14:54:29

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
DataPoint Un-verified.	Nia Moragne-O'Neal	23 Feb 2021 16:37:48
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Nia Moragne-O'Neal	23 Feb 2021 16:37:48
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	(b) (4), (b) (6)	27 Jan 2021 09:50:34
' (Site from DM).		
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	Ian Feather (b) (4)	25 Jan 2021 15:54:37
' answered with 'confirmed as ongoing ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	(b) (4), (b) (6)	21 Jan 2021 05:32:07
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'Yes (Y)'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
DataPoint Un-verified.	Nia Moragne-O'Neal	23 Feb 2021 16:37:48
	(b) (4)	
User entered '18 Nov 2020' reason for change: New Information	Nia Moragne-O'Neal	23 Feb 2021 16:37:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Form: Adverse Events (3)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:33
User entered empty.	System	19 Nov 2020 14:54:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:12:02
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' answered with 'see updated narrative' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:08:08
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 05:10:16
DataPoint Un-verified.	Nia Moragne-O'Neal	21 Dec 2020 16:46:58
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Nia Moragne-O'Neal	21 Dec 2020 16:46:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'No (N)'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'Not Related (NOT RELATED)'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'Not Related (NOT RELATED)'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User closed query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:57:03
Query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you.' answered with 'corrected' (Site from DM).	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:20:48
DataPoint Un-verified.	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:20:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:20:41
User opened query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 16:48:57
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'None (NONE)'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:54:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4) (b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		24 Feb 2021 16:58:26
User entered '0' reason for change: New Information	(b) (4), (b) (6)	24 Feb 2021 16:58:26
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	23 Feb 2021 16:37:48
User entered '1' reason for change: New Information	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 16:37:48
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#8) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 11:16:02
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#8) recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:07:28
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 17:07:22
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 17:07:22
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#8) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 05:10:43
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '1'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:54:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 17:07:22
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 17:07:22
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered '0'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
DataPoint Un-verified.	Nia Moragne-O'Neal	23 Feb 2021 16:37:48
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Nia Moragne-O'Neal	23 Feb 2021 16:37:48
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:33
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 16:07:56
User entered 'This AE was initially Grade 2 when it started but participant was started on tamsulosin and on 12/21 the grade was updated to Grade 1 because the AE improved.' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 16:07:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:41
User entered empty.	Lorna Sanchez McCann	19 Nov 2020 14:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:33
User entered '0'	System	19 Nov 2020 14:54:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:33
User entered '0'	System	19 Nov 2020 14:54:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User closed query 'Per DM CLR: Please note this AE overlaps with AE#3. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 10:05:06
Query 'Per DM CLR: Please note this AE overlaps with AE#3. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' answered with 'these should not be combined because they were together but due to a previous query stating that they should be separated, they were split into separate adverse events' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:05:48
User opened query 'Per DM CLR: Please note this AE overlaps with AE#3. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 05:10:55
User coded data point as SOC: Renal and urinary disorders, HLT: Urinary tract signs and symptoms, HLT: Urinary tract signs and symptoms NEC, PT: Nocturia, LLT: Nocturnal frequency - version MedDRA\23.0.	Coder Import (b) (4)	03 Dec 2020 07:51:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Dec 2020 07:51:56
Data point term sent to Coder	System	02 Dec 2020 18:23:41
User entered 'INCREASED NOCTURNAL URGENCY'	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:23:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '13 Nov 2020'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:38
User entered empty.	System	02 Dec 2020 18:23:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)' reason for change: New Information	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 16:38:15
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:23:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '18 Nov 2020' reason for change: New Information	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 16:38:15
User entered empty.	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:23:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:38
User entered empty.	System	02 Dec 2020 18:23:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Not Related (NOT RELATED)'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Not Related (NOT RELATED)'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Not Applicable (NOT APPLICABLE)'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'I'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Nia Moragne-O'Neal (b) (4)	23 Feb 2021 16:38:15
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lorna Sanchez McCann (b) (4)	02 Dec 2020 18:23:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	Lorna Sanchez McCann	02 Dec 2020 18:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:38
User entered '0'	System	02 Dec 2020 18:23:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:38
User entered '0'	System	02 Dec 2020 18:23:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 03:02:38

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 01:47:40
User entered	System	05 Jan 2021 18:18:32
'USA-US101-2021-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	05 Jan 2021 18:18:32

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular contractions - version MedDRA\23.0.	Coder Import (b) (4)	19 Apr 2021 20:22:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. DataPoint Verified.	Coder Import (b) (4)	19 Apr 2021 20:22:44
	(b) (4), (b) (6)	19 Apr 2021 19:27:16
Data point term sent to Coder DataPoint Un-verified.	System	15 Apr 2021 21:19:21
	Andrea Wendrow (b) (4)	15 Apr 2021 21:18:57
	(b) (4)	
Coding entries removed.	Andrea Wendrow (b) (4)	15 Apr 2021 21:18:57
	(b) (4)	
User entered 'CHEST PRESSURE - RESPIRATORY/SHORTNESS OF BREATH - CARDIAC RELATED from PVCs' reason for change: Per Query Resolution DataPoint Verified.	Andrea Wendrow (b) (4)	15 Apr 2021 21:18:57
	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Chest pain - cardiac - version MedDRA\23.0.	Coder Import (b) (4)	09 Feb 2021 12:22:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Feb 2021 12:22:46
	(b) (4)	
User closed query 'Per CDM re-query: Thank you for updating the AE term. Per previous query, please include non cardiac / cardiac along with AE term. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:17:17
Data point term sent to Coder	System	01 Feb 2021 17:41:04
Query 'Per CDM re-query: Thank you for updating the AE term. Per previous query, please include non cardiac / cardiac along with AE term. ' answered with 'updated, it is cardiac related. there will be more followup' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 17:40:38
User entered 'CHEST PRESSURE - RESPIRATORY/SHORTNESS OF BREATH - cardiac related' reason for change: New Information	(b) (4), (b) (6)	01 Feb 2021 17:40:22

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pressure is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 06:36:17
User opened query 'Per CDM re-query: Thank you for updating the AE term. Per previous query, please include non cardiac / cardiac along with AE term.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 06:36:15
Data point term sent to Coder	System	28 Jan 2021 18:33:35
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pressure is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 18:33:25
Coding entries removed.	(b) (4), (b) (6)	28 Jan 2021 18:33:19
User entered 'CHEST PRESSURE - respiratory/shortness of breath' reason for change: New Information	(b) (4), (b) (6)	28 Jan 2021 18:33:19
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pressure is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 08:26:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest pressure - version MedDRA\23.0.	(b) (4)	04 Jan 2021 17:26:40

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Andrea Wendrow (b) (4) (b) (4)	04 Jan 2021 17:26:40 04 Jan 2021 17:25:25 04 Jan 2021 17:24:59
User entered 'Chest Pressure' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	04 Jan 2021 17:24:59
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 16:58:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	04 Jan 2021 16:58:31 04 Jan 2021 16:57:53
User entered 'shortness of breath'	(b) (4), (b) (6) (b) (4)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '30 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
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	04 Jan 2021 17:25:40
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	04 Jan 2021 17:25:40
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	04 Jan 2021 17:24:59
User entered '06:47' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	04 Jan 2021 17:24:59
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 17:25:40
User entered '30 Dec 2020 06:47'	System	04 Jan 2021 17:24:59
User entered empty.	System	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 16:30:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:02:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
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	25 Feb 2021 16:31:27
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	25 Feb 2021 16:31:27
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	25 Feb 2021 16:30:55
User entered '30 Dec 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Feb 2021 16:30:55
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Feb 2021 17:07:38
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	24 Feb 2021 17:07:38
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Feb 2021 17:02:58
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Feb 2021 17:02:58
User entered '30 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

US3492273

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '30 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

US3492273

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:54:57
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Records faxed' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	23 Apr 2021 17:41:34
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:19:04
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '31 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

US3492273

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	04 Jan 2021 17:24:59
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User closed query 'Per CDM: AE start date is after first dose however Relationship to IP is reported as Not Applicable. Please review and update.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 12:13:19
Query 'Per CDM: AE start date is after first dose however Relationship to IP is reported as Not Applicable. Please review and update.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 21:45:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 21:44:55
User opened query 'Per CDM: AE start date is after first dose however Relationship to IP is reported as Not Applicable. Please review and update.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 15:06:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 15:40:17
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with '-----Corrected. thank you.-----' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:49:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 15:49:38
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:37:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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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.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:29:15
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'metoprolol succinate, updated indication' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:08:05
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:44:35
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User closed query 'Per CDM re-query: Previous response states 'updated dates' however date of 'ANGIOGRAM WITH STENT PLACEMENT' 18JAN2021, is still after the Stop Date for this AE. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 12:25:20
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 14:33:18
Query 'Per CDM re-query: Previous response states 'updated dates' however date of 'ANGIOGRAM WITH STENT PLACEMENT' 18JAN2021, is still after the Stop Date for this AE. Please review and update as appropriate.' answered with 'indication of "angiogram with stent placement" has been updated to medical history and the procedure box has been unchecked on this AE' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 14:32:26
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 14:31:41
User opened query 'Per CDM re-query: Previous response states 'updated dates' however date of 'ANGIOGRAM WITH STENT PLACEMENT' 18JAN2021, is still after the Stop Date for this AE. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:36:35
User closed query 'Per DM CLR - RQ: Site's response noted. However, ANGIOGRAM with STENT PLACEMENT were performed AFTER the STOP DATE of this AE. Please review and reconcile data as appropriate. Otherwise, record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:36:35

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR - RQ: Site's response noted. However, ANGIOGRAM with STENT PLACEMENT were performed AFTER the STOP DATE of this AE. Please review and reconcile data as appropriate. Otherwise, record a Medical Treatment Procedure as appropriate or update response to this field.' answered with 'updated dates' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:08:16
User opened query 'Per DM CLR - RQ: Site's response noted. However, ANGIOGRAM with STENT PLACEMENT were performed AFTER the STOP DATE of this AE. Please review and reconcile data as appropriate. Otherwise, record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 03:54:54
User closed query ' Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 10:02:37
Query ' Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'angiogram with stent placement' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:50:57
User opened query ' Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:44:28
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Feb 2021 16:31:27
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Feb 2021 17:07:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Form: Adverse Events (5)

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
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) (4), (b) (6)	26 Apr 2021 14:55:13
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 'Records faxed' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	23 Apr 2021 17:41:46
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)	23 Apr 2021 13:14:05
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User closed query 'Per DM CLR: Narrative = HISTORY OF STEMI MAR2019. However, in the MH eCRF, Myocardial Infarction date is UNK2019. Please review and verify if these data should be reconciled. Update applicable eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:38:15
User closed query 'Per DM CLR: Narrative = TROPONINS NEGATIVE X 3. 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)	26 Feb 2021 14:37:15
User closed query 'Per DM CLR: Narrative = FREQUENT PVCs. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:33:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WENT TO ER WITH SHORTNESS OF BREATH ON 30DEC2020. HISTORY OF STEMI MAR2019 AND ACS. NOTED TO BE IN STABLE CONDITION WITH NORMAL VITAL SIGNS. EKG SIGNIFICANT FOR SINUS RHYTHM WITH FREQUENT PVCS. TROPONINS NEGATIVE X 3. NO CHEMICAL EVIDENCE OF MI. ECHO STRESS TEST SIGNIFICANT FOR DISCRETE APICAL WALL MOTION ABNORMALITY POST EXERCISE. METOPROLOL STARTED. OVERNIGHTED FOR OBSERVATION. TO FOLLOW UP WITH CARDIOLOGIST AS OUTPATIENT IN 2 WEEKS. DISCHARGED IN STABLE CONDITION returned 18jan for angiogram with stent placement' reason for change: New Information	(b) (4), (b) (6)	25 Feb 2021 16:19:46
Query 'Per DM CLR: Narrative = FREQUENT PVCS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.	(b) (4), (b) (6)	25 Feb 2021 16:18:31
' answered with 'PVCs were not clinically significant' (Site from DM).		
Query 'Per DM CLR: Narrative = TROPONINS NEGATIVE X 3. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:17:14
Query 'Per DM CLR: Narrative = HISTORY OF STEMI MAR2019. However, in the MH eCRF, Myocardial Infarction date is UNK2019. Please review and verify if these data should be reconciled. Update applicable eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:12:46
User opened query 'Per DM CLR: Narrative = FREQUENT PVCS. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.	(b) (4), (b) (6)	23 Feb 2021 03:53:15
' (Site from DM).		

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = TROPONINS NEGATIVE X 3. 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)	08 Feb 2021 07:44:23
User opened query 'Per DM CLR: Narrative = HISTORY OF STEMI MAR2019. However, in the MH eCRF, Myocardial Infarction date is UNK2019. Please review and verify if these data should be reconciled. Update applicable eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:44:11
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Jan 2021 17:24:59
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	04 Jan 2021 17:24:59
User entered 'Participant went to ER with shortness of breath on 30Dec2020. History of STEMI Mar2019 and ACS. Noted to be in stable condition with normal vital signs. EKG significant for sinus rhythm with frequent PVCs. Troponins negative x 3. No chemical evidence of MI. Echo stress test significant for discrete apical wall motion abnormality post exercise. Metoprolol started. Overnighted for observation. To follow up with cardiologist as outpatient in 2 weeks. Discharged in stable condition' reason for change: New Information	Andrea Wendrow (b) (4)	04 Jan 2021 17:24:59
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Jan 2021 16:57:10
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '0'	System	04 Jan 2021 16:57:10

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:22:18
User entered	System	08 Feb 2021 12:21:35
'USA-US101-2021-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	08 Feb 2021 12:21:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 22:05:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 22:05:49
Data point term sent to Coder	System	05 Feb 2021 22:05:25
User entered 'Appendicitis'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '30 Jan 2021'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '5 Feb 2021'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Grade 4 (Grade 4)'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'I'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '30 Jan 2021'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '5 Feb 2021'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

US3492273

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Feb 2021 15:46:53
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 14:58:19
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)	02 Mar 2021 14:58:07
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 14:35:40
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 'nasal swab on 18 JAN 2021 and 30 JAN 2021 also nasal PCR on 30 Jan 2021' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 14:30:24
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:57:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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)	11 Feb 2021 16:56:59
User entered 'I'	Andrea Wendrow (b) (4)	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:35:27
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'records faxed' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 22:05:45
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 18:49:58
User closed query 'PV Query: Please provide the results of COVID-19 tests performed on 18 Jan 2021 and 30 Jan 2021.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 16:12:06
Query 'PV Query: Please provide the results of COVID-19 tests performed on 18 Jan 2021 and 30 Jan 2021.' answered with 'both results were" not detected"' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 22:34:10
User opened query 'PV Query: Please provide the results of COVID-19 tests performed on 18 Jan 2021 and 30 Jan 2021.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 06:27:32
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'subject awoke on 30Jan2021 with abdominal pain. Dx with appendicitis in ER, admitted and appendectomy performed 01Feb2021. Discharged 05Feb2021'	Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:04:56

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered 'I'	System	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered 'I'	System	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '0'	System	05 Feb 2021 22:04:56

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 19:36:11
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:32:47
User entered	(b) (4), (b) (6)	31 Mar 2021 16:18:51
'USA-US101-2021-mRNA-1273-P301000005'		

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Streptococcal infection, LLT: Streptococcal infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	07 Apr 2021 11:05:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. DataPoint Verified.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:05:32
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
Data point term sent to Coder	System	01 Mar 2021 14:43:10
User entered 'streptococcal anginosus blood stream infection'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 19:27:16
User closed query 'PV Query: Streptococcal anginosus blood stream infection was reported to have started on 30 Jan 2021. In case narrative, event was reported as post-appendectomy, which occurred on 01 Feb 2021. Please confirm start date of event, streptococcal anginosus blood stream infection.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:35:51
Query 'PV Query: Streptococcal anginosus blood stream infection was reported to have started on 30 Jan 2021. In case narrative, event was reported as post-appendectomy, which occurred on 01 Feb 2021. Please confirm start date of event, streptococcal anginosus blood stream infection.' answered with 'Blood cultures drawn 30JAN2021 and reported on 03FEB2021' (Site from Safety).	Marla Schwarber (b) (4)	16 Apr 2021 21:56:06
	(b) (4)	
User entered '30 Jan 2021' reason for change: Data Entry Error	Marla Schwarber (b) (4)	16 Apr 2021 21:54:55
	(b) (4)	
User opened query 'PV Query: Streptococcal anginosus blood stream infection was reported to have started on 30 Jan 2021. In case narrative, event was reported as post-appendectomy, which occurred on 01 Feb 2021. Please confirm start date of event, streptococcal anginosus blood stream infection.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 18:51:43
User closed query 'PV Query: Streptococcal anginosus blood stream infection was reported to have started on 30 Jan 2021. In case narrative, event was reported as post-appendectomy, which occurred on 01 Feb 2021. Please confirm start date of event, streptococcal anginosus blood stream infection.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 18:41:23
Query 'PV Query: Streptococcal anginosus blood stream infection was reported to have started on 30 Jan 2021. In case narrative, event was reported as post-appendectomy, which occurred on 01 Feb 2021. Please confirm start date of event, streptococcal anginosus blood stream infection.' answered with 'corrected' (Site from Safety).	Andrea Wendrow (b) (4)	15 Apr 2021 21:01:55
	(b) (4)	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Wendrow (b) (4)	15 Apr 2021 21:01:34
User entered '01 Feb 2021' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	15 Apr 2021 21:01:34
User opened query 'PV Query: Streptococcal anginosus blood stream infection was reported to have started on 30 Jan 2021. In case narrative, event was reported as post-appendectomy, which occurred on 01 Feb 2021. Please confirm start date of event, streptococcal anginosus blood stream infection.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:11:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '30 Jan 2021'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

US3492273

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:42:31

US3492273

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 19:36:11
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	30 Mar 2021 22:37:37
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	30 Mar 2021 22:37:37
DataPoint Un-verified.	Andrea Wendrow (b) (4)	30 Mar 2021 22:37:37
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	30 Mar 2021 22:37:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	01 Mar 2021 14:42:31
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:11
DataPoint Un-verified.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 22:37:37
User entered '1' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	30 Mar 2021 22:37:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:11
DataPoint Un-verified.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 22:37:37
User entered '30 Jan 2021' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 22:37:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:11
DataPoint Un-verified.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 22:37:37
User entered '05 Feb 2021' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 22:37:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:11
DataPoint Un-verified.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 22:37:37
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 22:37:37
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:11
User closed query 'PV Query: Action taken with study drug for event streptococcal anginosus blood stream infection, was reported as none. Please update action taken with study drug from none to no applicable as subject received both scheduled doses of study drug.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:32:55
Query 'PV Query: Action taken with study drug for event streptococcal anginosus blood stream infection, was reported as none. Please update action taken with study drug from none to no applicable as subject received both scheduled doses of study drug.' answered with 'corrected' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	09 Apr 2021 19:24:46
DataPoint Un-verified.	Marla Schwarber (b) (4) (b) (4)	09 Apr 2021 19:24:33
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	09 Apr 2021 19:24:33
User opened query 'PV Query: Action taken with study drug for event streptococcal anginosus blood stream infection, was reported as none. Please update action taken with study drug from none to no applicable as subject received both scheduled doses of study drug.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:11:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'None (NONE)'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User closed query 'Per CDM re-query: Response indicates corrected; However there is no con med record in the con med eCRF. Please review and add the con med else update the 'Oher action taken' as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:47:22
Query 'Per CDM re-query: Response indicates corrected; However there is no con med record in the con med eCRF. Please review and add the con med else update the 'Oher action taken' as appropriate. Thank you. ' answered with 'Con med added' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:55:04
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:36:51
User opened query 'Per CDM re-query: Response indicates corrected; However there is no con med record in the con med eCRF. Please review and add the con med else update the 'Oher action taken' as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:36:49
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	15 Apr 2021 21:02:12
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:16
User closed query 'PV Query: As event was reported as streptococcal anginosus blood stream infection, if a blood culture was collected to confirm diagnosis, please provide date and results of blood cultures or other diagnostic tests.' (Site from Safety). Query 'PV Query: As event was reported as streptococcal anginosus blood stream infection, if a blood culture was collected to confirm diagnosis, please provide date and results of blood cultures or other diagnostic tests.' answered with 'per discharge note, not available' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 18:41:35
DataPoint Un-verified.	Andrea Wendrow (b) (4) (b) (4)	15 Apr 2021 21:02:55
User entered '1' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	15 Apr 2021 21:01:34
User opened query 'PV Query: As event was reported as streptococcal anginosus blood stream infection, if a blood culture was collected to confirm diagnosis, please provide date and results of blood cultures or other diagnostic tests.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 15:12:32
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User closed query 'PV Query: As event was reported as streptococcal anginosus blood stream infection, if a blood culture was collected to confirm diagnosis, please provide date and results of blood cultures or other diagnostic tests.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:36:03
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:36:00
Query 'PV Query: As event was reported as streptococcal anginosus blood stream infection, if a blood culture was collected to confirm diagnosis, please provide date and results of blood cultures or other diagnostic tests.' answered with 'records faxed' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 22:05:14
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'records faxed' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 22:05:04
User opened query 'PV Query: As event was reported as streptococcal anginosus blood stream infection, if a blood culture was collected to confirm diagnosis, please provide date and results of blood cultures or other diagnostic tests.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 18:52:15
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 18:51:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:46
User entered 'post-appendectomy, took antibiotics'	(b) (4), (b) (6)	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 22:37:37
User entered '0'	System	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 14:42:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '0'	System	30 Mar 2021 22:37:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:27
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:13:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Dec 2020 20:20:53
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 Dec 2020 20:20:53
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	11 Dec 2020 15:40:27 11 Dec 2020 15:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:47:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:47:50
Data point term sent to Coder User entered 'diclofenac'	System (b) (4), (b) (6)	01 Oct 2020 13:13:42 01 Oct 2020 13:13:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:13:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 07:10:04
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'med history updated' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 15:40:07
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 15:39:46
User entered 'pain from arthritis to right knee' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 15:39:46
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 07:07:59
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'muscle pain'	(b) (4), (b) (6)	01 Oct 2020 13:13:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:21:56
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 14:03:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Dec 2020 14:03:32
User entered '75' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 14:03:32
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 07:08:08
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '5'	(b) (4), (b) (6)	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'un UNK 2020'	(b) (4), (b) (6)	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:13:35

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Dec 2020 20:18:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Dec 2020 20:18:48
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	11 Dec 2020 15:42:29 11 Dec 2020 15:42:08
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 13:15:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 13:15:47
Data point term sent to Coder User entered 'cyclobenzaprine'	System (b) (4), (b) (6)	01 Oct 2020 13:14:47 01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:42:08
User entered 'PAIN from LEFT SHOULDER ROTATOR TEAR' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 15:42:08
DataPoint Verified.	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'muscle pain'	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '5'	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'un UNK 2020'	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 13:13:58

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
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)	01 Oct 2020 13:15:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:15:48
Data point term sent to Coder	System	01 Oct 2020 13:14:47
User entered 'lisinopril'	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'hypertension'	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '20'	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'un UNK 2020'	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 13:14:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:18:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:18:32
Data point term sent to Coder	System	01 Oct 2020 13:16:49
User entered 'pneumovax'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'preventative care'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'unk'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'unk'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '01 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '01 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User entered empty.	System	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User entered empty.	System	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:03
User entered empty.	System	01 Oct 2020 13:15:49

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:17:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 13:17:49
Data point term sent to Coder	System	01 Oct 2020 13:16:50
User entered 'shingrix'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'preventative care'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'unk'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'unk'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'once (ONCE)'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '01 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '01 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User entered empty.	System	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User entered empty.	System	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:07
User entered empty.	System	01 Oct 2020 13:16:43

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:29:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:29:29
Data point term sent to Coder	System	15 Oct 2020 15:41:28
User entered 'Amoxicillin'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Prior to dental work'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '2000'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'mg (mg)'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
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	15 Oct 2020 15:41:32
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	15 Oct 2020 15:41:32
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	15 Oct 2020 15:40:59
User entered 'once (ONCE)'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'Oral (ORAL)'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered empty.	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '9 Oct 2020'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '0'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered '9 Oct 2020' reason for change: Per Query Resolution	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:41:32
User entered '10 Oct 2020'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:12:12
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User entered empty.	System	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User entered empty.	System	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:11
User entered empty.	System	15 Oct 2020 15:40:59

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:13:51
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 14:52:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 14:52:59
	(b) (4)	
Data point term sent to Coder	System	19 Nov 2020 14:51:40
User entered 'Tamsulosin'	Lorna Sanchez McCann	19 Nov 2020 14:51:31
	(b) (4)	

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
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)	28 Jan 2021 13:11:08
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 'medical history updated' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 17:48:54
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)	22 Jan 2021 07:03:12
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered 'Benign Prostatic Hyperplasia'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered '0.4'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered 'mg (mg)'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered empty.	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered 'once daily (QD)'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered empty.	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered 'Oral (ORAL)'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered empty.	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered '14 Nov 2020'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered '0'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered empty.	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:13:51
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 14:51:31

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 19:12:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 19:12:44
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	11 Dec 2020 15:55:39
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 09:51:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 09:51:48
Data point term sent to Coder User entered 'flomax'	System (b) (4), (b) (6)	07 Dec 2020 14:06:22
		07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'URINARY FREQUECNY OF UNKNOWN ORIGIN' reason for change: New Information	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:55:17
User entered 'unknown'	(b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0.4'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Dec 2020 14:05:23

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:30
Data point term sent to Coder	System	21 Dec 2020 16:51:02
User entered 'Influenza vaccine'	Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'prevent influenza'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'unk'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Other (OTHER)'	Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'unk'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'once (ONCE)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '23 Nov 2020'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '23 Nov 2020'	Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
User entered empty.	System	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
User entered empty.	System	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:18
User entered empty.	System	21 Dec 2020 16:50:37

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Dec 2020 21:56:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Dec 2020 21:56:55
Data point term sent to Coder	System	21 Dec 2020 16:52:03
User entered 'Shingles vaccine'	Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'prevent shingles'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'unk'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Other (OTHER)'	Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'unk'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'once (ONCE)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '23 Nov 2020'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '23 Nov 2020'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) Nia Moragne-O'Neal (b) (4)	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
User entered empty.	System	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
User entered empty.	System	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:22
User entered empty.	System	21 Dec 2020 16:51:45

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:05:07
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 Feb 2021 07:05:07
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	24 Feb 2021 16:54:32 24 Feb 2021 16:54:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:30:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:42:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:42:31
Data point term sent to Coder User entered 'metoprolol succinate'	System (b) (4), (b) (6)	04 Jan 2021 17:35:38 04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
User closed query 'Per DM CLR: Response noted on previous query. However, Chest Pressure-Respiratory/ Shortness of Breath stop date=30 DEC 2020. Please note that there is no ongoing AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify '(Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:58:37
Query 'Per DM CLR: Response noted on previous query. However, Chest Pressure-Respiratory/ Shortness of Breath stop date=30 DEC 2020. Please note that there is no ongoing AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify ' answered with 'Adjusted AE to include PVCs. Event resolved however medication is continued as treatment' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	15 Apr 2021 21:20:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User opened query 'Per DM CLR: Response noted on previous query. However, Chest Pressure-Respiratory/ Shortness of Breath stop date=30 DEC 2020. Please note that there is no ongoing AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify '(Site from DM).	(b) (4), (b) (6)	13 Mar 2021 08:05:47
User closed query 'Per DM CLR: Please note there is no 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 AE eCRF.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:55:22

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no 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 AE eCRF.'	(b) (4), (b) (6)	24 Feb 2021 16:54:52
answered with 'updated, this medication is noted as being started in the narrative of the AE that starts with "chest pressure"' (Site from DM).		
Signature has been broken.	(b) (4), (b) (6)	24 Feb 2021 16:54:18
User entered 'PREMATURE VENTRICULAR CONTRACTIONS - in relation to chest pressure AE'	(b) (4), (b) (6)	24 Feb 2021 16:54:18
reason for change: Data Entry Error		
User opened query 'Per DM CLR: Please note there is no 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 AE eCRF.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:55:05
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Premature Ventricular Contractions'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '25'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '31 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Jan 2021 17:35:18

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
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)	20 Jan 2021 14:11:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	20 Jan 2021 14:11:13
Data point term sent to Coder	System	20 Jan 2021 14:10:26
User entered 'aspirin'	(b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'health maintenance'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '81'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 14:09:47

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 14:28:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 14:28:03
Data point term sent to Coder	System	20 Jan 2021 14:11:35
User entered 'plavix'	(b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'post-procedure stent'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '75'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 14:10:26

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 14:13:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 14:13:03
Data point term sent to Coder	System	20 Jan 2021 14:11:35
User entered 'crestor'	(b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:37:40
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'added to medical history' (Site from DM).	Andrea Wendrow (b) (4)	15 Apr 2021 21:09:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:26:23
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'hyperlipidemia'	(b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '20'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 14:10:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:40
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: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:11:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:11:08
Data point term sent to Coder	System	01 Mar 2021 14:37:59
Coding entries removed.	(b) (4), (b) (6)	01 Mar 2021 14:37:36
Signature has been broken.	(b) (4), (b) (6)	01 Mar 2021 14:37:36
User entered 'Augmentin clavulanic 875/125 mg' reason for change: New Information	(b) (4), (b) (6)	01 Mar 2021 14:37:36
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:30:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 08:21:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 08:21:53
Data point term sent to Coder	System	05 Feb 2021 22:14:30
User entered 'amoxicillin'	(b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
User closed query 'Per ETRTR: Procedure was performed on 30Jan21 related to SAE "Apendicitis". Please go to SAE page and tick within "Concomitant Medication" Action Taken checkbox, thanks' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:03:39
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
Query 'Per ETRTR: Procedure was performed on 30Jan21 related to SAE "Apendicitis". Please go to SAE page and tick within "Concomitant Medication" Action Taken checkbox, thanks' answered with 'completed' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 15:47:09
User opened query 'Per ETRTR: Procedure was performed on 30Jan21 related to SAE "Apendicitis". Please go to SAE page and tick within "Concomitant Medication" Action Taken checkbox, thanks' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 03:56:23
Query 'Procedure was performed on 30Jan21 related to SAE "Apendicitis". Please go to SAE page and tick within "Concomitant Medication" Action Taken checkbox, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 03:56:13
User opened query 'Procedure was performed on 30Jan21 related to SAE "Apendicitis". Please go to SAE page and tick within "Concomitant Medication" Action Taken checkbox, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 03:55:43
Query 'Per ETRTR: Procedure was performed on 30Jan21 related to SAE "Apendicitis". Please go to SAE page and tick within "Concomitant Procedures" Action Taken checkbox, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 03:53:59
User opened query 'Per ETRTR: Procedure was performed on 30Jan21 related to SAE "Apendicitis". Please go to SAE page and tick within "Concomitant Procedures" Action Taken checkbox, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 03:53:33
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Post-appendectomy antibiotic coverage'	(b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:40
Signature has been broken.	(b) (4), (b) (6)	01 Mar 2021 14:37:36
User entered '1' reason for change: New Information	(b) (4), (b) (6)	01 Mar 2021 14:37:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '1250'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:40
Signature has been broken.	(b) (4), (b) (6)	01 Mar 2021 14:37:36
User entered 'tablet (TABLET)' reason for change: New Information	(b) (4), (b) (6)	01 Mar 2021 14:37:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:40
Signature has been broken.	(b) (4), (b) (6)	01 Mar 2021 14:37:36
User entered 'three times daily (TID)' reason for change: New Information	(b) (4), (b) (6)	01 Mar 2021 14:37:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:40
Signature has been broken.	(b) (4), (b) (6)	01 Mar 2021 14:37:36
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	01 Mar 2021 14:37:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:40
Signature has been broken.	(b) (4), (b) (6)	01 Mar 2021 14:37:36
User entered '13 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	01 Mar 2021 14:37:36
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
User entered '3'	System	01 Mar 2021 14:37:36
User entered '2'	System	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
User entered '1'	System	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:31
User entered '804 (804)'	System	05 Feb 2021 22:14:09

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Feb 2021 22:19:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Feb 2021 22:19:49
Data point term sent to Coder	System	05 Feb 2021 22:19:32
User entered 'docusate sodium'	(b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'stool softener'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '100'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '2'	System	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 22:18:54

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
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)	05 Feb 2021 22:22:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 22:22:49
Data point term sent to Coder	System	05 Feb 2021 22:22:33
User entered 'acetaminophen'	(b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'post-operative pain'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '650'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:22:00

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
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: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:21:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:21:48
Data point term sent to Coder	System	16 Apr 2021 14:54:22
User entered 'Piperacillin/tazobactam (Zosyn)'	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered 'STREPTOCOCCAL ANGINOSUS BLOOD STREAM INFECTION'	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered '3.375'	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered 'g (g)'	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered empty.	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered 'three times daily (TID)'	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered empty.	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered 'Intravenous (INTRAVENOUS)'	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered empty.	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered '01 Feb 2021'	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered '0'	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered '05 Feb 2021'	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:40
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User entered '3'	System	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User entered '1'	System	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:42:37
User entered '804 (804)'	System	16 Apr 2021 14:54:20

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:02:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:34
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Jan 2021 17:27:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 13:12:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 13:10:35

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:02:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
Signature has been broken.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:34:16
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:47

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:02:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Exercise stress echo'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:47

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:47

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:02:29

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:29:47

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:02:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:30:01

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:02:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'EKG'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:30:01

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:30:01

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:02:29

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:30:01

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:02:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:30:46

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:02:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'CHEST X-RAY 1 view'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:30:46

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:30:46

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:02:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 17:30:46

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:02:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User closed query 'Per DM CLR-RQ: Response noted as "updated". However, recorded date is still not within the timeframe of the corresponding AE (AE#5 30DEC2020 - 30DEC2020). Please reconcile and update to procedure date as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:03:02
Query 'Per DM CLR-RQ: Response noted as "updated". However, recorded date is still not within the timeframe of the corresponding AE (AE#5 30DEC2020 - 30DEC2020). Please reconcile and update to procedure date as appropriate, otherwise clarify.' answered with 'the indication was changed to medical history' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 13:38:33
User opened query 'Per DM CLR-RQ: Response noted as "updated". However, recorded date is still not within the timeframe of the corresponding AE (AE#5 30DEC2020 - 30DEC2020). Please reconcile and update to procedure date as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:01:49
User closed query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe of AE #5 CHEST PRESSURE - RESPIRATORY/SHORTNESS OF BREATH - CARDIAC RELATED (30 DEC 2020-30 DEC 2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:54:46
Query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe of AE #5 CHEST PRESSURE - RESPIRATORY/SHORTNESS OF BREATH - CARDIAC RELATED (30 DEC 2020-30 DEC 2020). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:09:41

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:02:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe of AE #5 CHEST PRESSURE - RESPIRATORY/SHORTNESS OF BREATH - CARDIAC RELATED (30 DEC 2020-30 DEC 2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	25 Feb 2021 07:46:45
	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '18 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 14:12:11

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:02:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'angiogram with stent placement'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:12:11

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
Signature has been broken.	(b) (4) (b) (4), (b) (6)	28 Feb 2021 20:55:40
User entered 'Medical History (MH)' reason for change: Per Query Resolution	(b) (4), (b) (6)	28 Feb 2021 20:55:40
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:12:11

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:02:29

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:12:11

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:02:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '1 Feb 2021'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:05:54

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:02:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Appendectomy'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:05:54

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'Adverse Event (AE)'	(b) (4) Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:05:54

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:02:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:58
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered empty.	(b) (4) Andrea Wendrow (b) (4) (b) (4)	05 Feb 2021 22:05:54

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:02:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:16:57

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:02:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered 'ACS rule out with troponin negative x3'	(b) (4), (b) (6)	25 Feb 2021 16:16:57

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:16:57

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:02:29

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:00
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:16:57

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:02:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered '30 Jan 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:35:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:35:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Mar 2021 14:34:16

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:02:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered 'blood cultures'	(b) (4), (b) (6)	01 Mar 2021 14:35:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:35:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Mar 2021 14:34:16

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:02:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:35:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:35:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Mar 2021 14:34:16

US3492273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 08:02:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:56:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:37
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:35:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	01 Mar 2021 14:35:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Mar 2021 14:34:16

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'USA-US101-2021-MRNA-1273-P301000001'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Richard'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Novak'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '808 S. Wood St'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Chicago'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'IL'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '60612'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'US'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '8'	System	16 Apr 2021 18:12:49
User entered '7'	System	02 Mar 2021 16:42:08
Signature has been broken.	System	26 Feb 2021 01:48:08
User entered '6'	System	26 Feb 2021 01:48:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '5'	System	08 Feb 2021 12:18:58
User entered '4'	System	02 Feb 2021 15:17:47
User entered '3'	System	29 Jan 2021 17:08:55
User entered '2'	System	13 Jan 2021 15:42:05
User entered '1'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'USA-US101-2021-MRNA-1273-P301000001'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Richard'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Novak'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '808 S. Wood St'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Chicago'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'IL'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '60612'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'US'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '8'	System	16 Apr 2021 18:12:49
User entered '7'	System	02 Mar 2021 16:42:08
Signature has been broken.	System	26 Feb 2021 01:48:08
User entered '6'	System	26 Feb 2021 01:48:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '5'	System	08 Feb 2021 12:18:58
User entered '4'	System	02 Feb 2021 15:17:47
User entered '3'	System	29 Jan 2021 17:08:55
User entered '2'	System	13 Jan 2021 15:42:05
User entered '1'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '05/Jan/2021 13:19'	(b) (4) System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'I'	(b) (4), (b) (6)	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'USA-US101-2021-MRNA-1273-P301000001'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Richard'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Novak'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '808 S. Wood St'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Chicago'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'IL'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '60612'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'US'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '8'	System	16 Apr 2021 18:12:49
User entered '7'	System	02 Mar 2021 16:42:08
Signature has been broken.	System	26 Feb 2021 01:48:08
User entered '6'	System	26 Feb 2021 01:48:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '5'	System	08 Feb 2021 12:18:58
User entered '4'	System	02 Feb 2021 15:17:47
User entered '3'	System	29 Jan 2021 17:08:55
User entered '2'	System	13 Jan 2021 15:42:05
User entered '1'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '13/Jan/2021 10:42'	(b) (4) System	13 Jan 2021 15:42:05

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4), (b) (6)	13 Jan 2021 15:42:10
User entered 'I'	(b) (4), (b) (6)	13 Jan 2021 15:42:05

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'USA-US101-2021-MRNA-1273-P301000001'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Richard'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Novak'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '808 S. Wood St'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Chicago'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'IL'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '60612'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'US'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '8'	System	16 Apr 2021 18:12:49
User entered '7'	System	02 Mar 2021 16:42:08
Signature has been broken.	System	26 Feb 2021 01:48:08
User entered '6'	System	26 Feb 2021 01:48:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '5'	System	08 Feb 2021 12:18:58
User entered '4'	System	02 Feb 2021 15:17:47
User entered '3'	System	29 Jan 2021 17:08:55
User entered '2'	System	13 Jan 2021 15:42:05
User entered '1'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '29/Jan/2021 17:08'	(b) (4) System	29 Jan 2021 17:08:55

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:17:38
User entered '1'	(b) (4), (b) (6)	29 Jan 2021 17:08:55

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'USA-US101-2021-MRNA-1273-P301000001'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Richard'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Novak'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '808 S. Wood St'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Chicago'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'IL'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '60612'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'US'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '8'	System	16 Apr 2021 18:12:49
User entered '7'	System	02 Mar 2021 16:42:08
Signature has been broken.	System	26 Feb 2021 01:48:08
User entered '6'	System	26 Feb 2021 01:48:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '5'	System	08 Feb 2021 12:18:58
User entered '4'	System	02 Feb 2021 15:17:47
User entered '3'	System	29 Jan 2021 17:08:55
User entered '2'	System	13 Jan 2021 15:42:05
User entered '1'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '02/Feb/2021 15:17'	(b) (4) System	02 Feb 2021 15:17:47

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:18:47
User entered '1'	(b) (4), (b) (6)	02 Feb 2021 15:17:47

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'USA-US101-2021-MRNA-1273-P301000001'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Richard'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Novak'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '808 S. Wood St'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Chicago'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'IL'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '60612'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'US'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '8'	System	16 Apr 2021 18:12:49
User entered '7'	System	02 Mar 2021 16:42:08
Signature has been broken.	System	26 Feb 2021 01:48:08
User entered '6'	System	26 Feb 2021 01:48:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '5'	System	08 Feb 2021 12:18:58
User entered '4'	System	02 Feb 2021 15:17:47
User entered '3'	System	29 Jan 2021 17:08:55
User entered '2'	System	13 Jan 2021 15:42:05
User entered '1'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '08/Feb/2021 12:18'	(b) (4) System	08 Feb 2021 12:18:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 01:47:53
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 12:18:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'USA-US101-2021-MRNA-1273-P301000001'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Richard'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Novak'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '808 S. Wood St'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Chicago'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'IL'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '60612'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'US'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '8'	System	16 Apr 2021 18:12:49
User entered '7'	System	02 Mar 2021 16:42:08
Signature has been broken.	System	26 Feb 2021 01:48:08
User entered '6'	System	26 Feb 2021 01:48:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '5'	System	08 Feb 2021 12:18:58
User entered '4'	System	02 Feb 2021 15:17:47
User entered '3'	System	29 Jan 2021 17:08:55
User entered '2'	System	13 Jan 2021 15:42:05
User entered '1'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:33:00
User entered '25/Feb/2021 20:48'	System	26 Feb 2021 01:48:08

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:33:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 16:41:53
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 01:48:08

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'USA-US101-2021-MRNA-1273-P301000001'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Richard'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Novak'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '808 S. Wood St'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Chicago'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'IL'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '60612'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'US'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '8'	System	16 Apr 2021 18:12:49
User entered '7'	System	02 Mar 2021 16:42:08
Signature has been broken.	System	26 Feb 2021 01:48:08
User entered '6'	System	26 Feb 2021 01:48:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '5'	System	08 Feb 2021 12:18:58
User entered '4'	System	02 Feb 2021 15:17:47
User entered '3'	System	29 Jan 2021 17:08:55
User entered '2'	System	13 Jan 2021 15:42:05
User entered '1'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:33:00
User entered '02/Mar/2021 16:42'	System	02 Mar 2021 16:42:08

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:12:30
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:33:00
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 16:42:08

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'USA-US101-2021-MRNA-1273-P301000001'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Yes (Y)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'No (N)'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Richard'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Novak'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '808 S. Wood St'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'Chicago'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'IL'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered '60612'	System	05 Jan 2021 18:18:32

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:00
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:19:12
User entered 'US'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '8'	System	16 Apr 2021 18:12:49
User entered '7'	System	02 Mar 2021 16:42:08
Signature has been broken.	System	26 Feb 2021 01:48:08
User entered '6'	System	26 Feb 2021 01:48:08
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '5'	System	08 Feb 2021 12:18:58
User entered '4'	System	02 Feb 2021 15:17:47
User entered '3'	System	29 Jan 2021 17:08:55
User entered '2'	System	13 Jan 2021 15:42:05
User entered '1'	System	05 Jan 2021 18:19:09

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:26:55
User entered '16/Apr/2021 14:12'	System	16 Apr 2021 18:12:49

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:26:55
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 18:12:49

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'USA-US101-2021-MRNA-1273-P301000005'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Richard'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Novak'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '808 S. Wood St'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Chicago'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'IL'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '60612'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 18:02:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'US'	(b) (4) System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 13:14:16
User entered '5'	System	16 Apr 2021 18:38:44
User entered '4'	System	12 Apr 2021 13:33:29
User entered '3'	System	31 Mar 2021 16:20:20
Signature has been broken.	System	26 Feb 2021 18:01:29
User entered '2'	System	26 Feb 2021 18:01:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '1'	System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'USA-US101-2021-MRNA-1273-P301000005'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Richard'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Novak'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '808 S. Wood St'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Chicago'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'IL'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '60612'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 18:02:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'US'	(b) (4) System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 13:14:16
User entered '5'	System	16 Apr 2021 18:38:44
User entered '4'	System	12 Apr 2021 13:33:29
User entered '3'	System	31 Mar 2021 16:20:20
Signature has been broken.	System	26 Feb 2021 18:01:29
User entered '2'	System	26 Feb 2021 18:01:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '1'	System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered '08/Feb/2021 12:22'	(b) (4) System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 18:02:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'USA-US101-2021-MRNA-1273-P301000005'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Richard'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Novak'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '808 S. Wood St'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Chicago'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'IL'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '60612'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 18:02:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'US'	(b) (4) System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 13:14:16
User entered '5'	System	16 Apr 2021 18:38:44
User entered '4'	System	12 Apr 2021 13:33:29
User entered '3'	System	31 Mar 2021 16:20:20
Signature has been broken.	System	26 Feb 2021 18:01:29
User entered '2'	System	26 Feb 2021 18:01:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '1'	System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:52
User entered '26/Feb/2021 13:01'	System	26 Feb 2021 18:01:29

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:55:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 18:02:06
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 18:01:29

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'USA-US101-2021-MRNA-1273-P301000005'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Richard'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Novak'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '808 S. Wood St'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Chicago'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'IL'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '60612'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 18:02:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'US'	(b) (4) System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 13:14:16
User entered '5'	System	16 Apr 2021 18:38:44
User entered '4'	System	12 Apr 2021 13:33:29
User entered '3'	System	31 Mar 2021 16:20:20
Signature has been broken.	System	26 Feb 2021 18:01:29
User entered '2'	System	26 Feb 2021 18:01:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '1'	System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:01
User entered '31/Mar/2021 12:20'	System	31 Mar 2021 16:20:20

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 18:38:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:01
User entered 'I'	(b) (4), (b) (6)	31 Mar 2021 16:20:20

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'USA-US101-2021-MRNA-1273-P301000005'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Richard'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Novak'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '808 S. Wood St'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Chicago'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'IL'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '60612'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 18:02:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'US'	(b) (4) System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 13:14:16
User entered '5'	System	16 Apr 2021 18:38:44
User entered '4'	System	12 Apr 2021 13:33:29
User entered '3'	System	31 Mar 2021 16:20:20
Signature has been broken.	System	26 Feb 2021 18:01:29
User entered '2'	System	26 Feb 2021 18:01:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '1'	System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 19:36:01
User entered '12/Apr/2021 09:33'	System	12 Apr 2021 13:33:29

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 18:38:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:36:01
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 13:33:29

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'USA-US101-2021-MRNA-1273-P301000005'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Richard'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Novak'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '808 S. Wood St'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Chicago'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'IL'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '60612'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 18:02:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'US'	(b) (4) System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 13:14:16
User entered '5'	System	16 Apr 2021 18:38:44
User entered '4'	System	12 Apr 2021 13:33:29
User entered '3'	System	31 Mar 2021 16:20:20
Signature has been broken.	System	26 Feb 2021 18:01:29
User entered '2'	System	26 Feb 2021 18:01:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '1'	System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:04
User entered '16/Apr/2021 14:38'	System	16 Apr 2021 18:38:44

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:04
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 18:38:44

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'USA-US101-2021-MRNA-1273-P301000005'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Yes (Y)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'No (N)'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Richard'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Novak'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '808 S. Wood St'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'Chicago'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered 'IL'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:22:47
User entered '60612'	System	08 Feb 2021 12:21:35

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:52
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 18:02:06
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
User entered 'US'	(b) (4) System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 13:14:16
User entered '5'	System	16 Apr 2021 18:38:44
User entered '4'	System	12 Apr 2021 13:33:29
User entered '3'	System	31 Mar 2021 16:20:20
Signature has been broken.	System	26 Feb 2021 18:01:29
User entered '2'	System	26 Feb 2021 18:01:29
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:30:29
	(b) (4)	
User entered '1'	System	08 Feb 2021 12:22:58

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:02:29

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:04
User entered '19/Apr/2021 06:14'	System	19 Apr 2021 13:14:16

US3492273

Folder: SAE USA-US101-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:02:29

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.

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:34:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:27:04
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 13:14:16