

US3042264 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:56:50

All time stamps listed in this document are displayed in GMT

US3042264

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Participant ID

US3042264

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

US3042264

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	68
Age Units	YEARS
Age (Derived)	68
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify _____	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number _____	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Condition	BILATERAL FOOT NEUROPATHY-SENSORY
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 (4)

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Condition	ACID REFLUX
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 (5)

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3042264

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

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

US3042264

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Condition	HEPATITIS A
Start date (dd MMM yyyy)	UN UNK 1991
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 UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

US3042264

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:05
Height (xxx.x)	185.4 cm
Weight (xxx.x)	109.5 kg
BMI (xxx.x)	31.85625 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 21:37:49

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

OUT IN COMMUNITY
FREQUENTLY WITHOUT MASK

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) 28 Apr 2021 21:37:49

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 187130

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) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

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) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

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)	20 AUG 2020
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:05
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	16:36 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 16:36
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 16:01 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 16:01

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) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	15:40 (24 HR)
Collection date and time (derived)	20 AUG 2020 15:40

US3042264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:27	20 AUG 2020 15:27
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 16:36

PC Open Date & Time

20 AUG 2020 16:21

PC Close Date & Time

20 AUG 2020 18:51

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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 ☒

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

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

PC Time Stamp	20 AUG 2020 19:50
PC Open Date & Time	20 AUG 2020 19:46
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 12:13

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

22 AUG 2020 12:02

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

23 AUG 2020 12:00

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 14:08

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

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

97.2 °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

25 AUG 2020 12:02

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

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

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

26 AUG 2020 12:01

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 16:37

PC Open Date & Time

20 AUG 2020 16:21

PC Close Date & Time

20 AUG 2020 18:51

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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

20 AUG 2020 19:51

PC Open Date & Time

20 AUG 2020 19:46

PC Close Date & Time

21 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

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

21 AUG 2020 12:14

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

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

22 AUG 2020 12:02

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

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

23 AUG 2020 12:01

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

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

24 AUG 2020 14:09

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

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

25 AUG 2020 12:02

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

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

26 AUG 2020 12:01

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 16:38
PC Open Date & Time	20 AUG 2020 16:21
PC Close Date & Time	20 AUG 2020 18:51

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 19:51
PC Open Date & Time	20 AUG 2020 19:46
PC Close Date & Time	21 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

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 ☒

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:15
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

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)

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:03
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

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 ☒

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:01
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

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)

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US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 14:09
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

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 ☒

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US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:02
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

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 ☒

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:01
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3042264

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:50

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:50

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

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)	17 SEP 2020
Time of assessment (00:00-23:59)	06:59 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 06:59
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	08:17 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 08:17
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3042264

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3042264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 07:43 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 07:43

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

US3042264

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 SEP 2020
Collection time (00:00-23:59)	07:10 (24 HR)
Collection date and time (derived)	17 SEP 2020 07:10

US3042264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:20	17 SEP 2020 07:20
Nasopharyngeal Swab 2	No		

US3042264

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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

98.6 °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

17 SEP 2020 08:11

PC Open Date & Time

17 SEP 2020 08:03

PC Close Date & Time

17 SEP 2020 10:33

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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 98.6 °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	17 SEP 2020 11:36
PC Open Date & Time	17 SEP 2020 11:28
PC Close Date & Time	18 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:00

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

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

97.6 °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

19 SEP 2020 12:01

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 12:16

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

21 SEP 2020 12:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

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

98.6 °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

23 SEP 2020 11:22

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

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

98.2 °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

23 SEP 2020 12:01

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 08:12

PC Open Date & Time

17 SEP 2020 08:03

PC Close Date & Time

17 SEP 2020 10:33

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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

17 SEP 2020 11:36

PC Open Date & Time

17 SEP 2020 11:28

PC Close Date & Time

18 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

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

18 SEP 2020 12:01

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

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

19 SEP 2020 12:01

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

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

20 SEP 2020 12:16

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

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

21 SEP 2020 12:01

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

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

23 SEP 2020 11:22

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

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

23 SEP 2020 12:01

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 08:14
PC Open Date & Time	17 SEP 2020 08:03
PC Close Date & Time	17 SEP 2020 10:33

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 11:36
PC Open Date & Time	17 SEP 2020 11:28
PC Close Date & Time	18 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

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 ☒

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:01
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

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 ☒

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:01
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

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 ☒

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 12:16
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

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 ☒

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 12:01
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

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 ☒

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 11:22
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

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 ☒

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US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 12:02
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3042264

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	VISIT3

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:05 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 08:05
Temperature (<i>xxx.x</i>)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3042264

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	08:12 (24 HR)
Collection date and time (derived)	15 OCT 2020 08:12

US3042264

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 07:05:56

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	28 OCT 2020 11:35:21
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 78

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

No ☒

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 NOV 2020 06:41:14

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 92

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

17 NOV 2020 08:26:15

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 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	23 NOV 2020 14:17:21
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

30 NOV 2020 19:32:37

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

05 DEC 2020 00:28:56

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☒

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 DEC 2020 00:02:45

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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	19 DEC 2020 10:26:58
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 09:15:56

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

02 JAN 2021 08:52:59

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

09 JAN 2021 00:26:08

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

16 JAN 2021 06:08:26

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

23 JAN 2021 00:13:44

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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	30 JAN 2021 09:02:09
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

06 FEB 2021 10:01:56

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

13 FEB 2021 08:45:58

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

20 FEB 2021 20:51:00

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 00:30:58

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

06 MAR 2021 01:22:55

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

13 MAR 2021 09:06:51

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

20 MAR 2021 11:07:52

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 07:52:59

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☒

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

03 APR 2021 00:05:31

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☒

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

10 APR 2021 08:16:04

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	17 APR 2021 07:44:02
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 01:37:23

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

Date and time of submission

01 MAY 2021 12:39:23

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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="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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAY 2021 00:01
Patient Cloud Close Date & Time	26 MAY 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐ 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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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°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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐
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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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°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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 <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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐ 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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐ 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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐ 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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐ 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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐ 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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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°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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01
Patient Cloud Close Date & Time	02 FEB 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 <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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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°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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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="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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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°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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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°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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐ 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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 <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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐ 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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	13 AUG 2022 00:01
Patient Cloud Close Date & Time	17 AUG 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	27 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3042264

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:56:50

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 11:06:44

US3042264

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:50

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:50

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:36:50

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:50

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3042264

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

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.

US3042264

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 MAR 2021
Collection time (00:00-23:59)	11:27 (24 HR)
Collection date and time (derived)	02 MAR 2021 11:27

US3042264

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:49

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

US3042264

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3042264

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:56:50

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"/>

US3042264

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:56:50

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3042264

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

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

Visit date (dd MMM yyyy)	13 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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US3042264

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Date of updated informed consent (<i>dd MMM yyyy</i>)	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3042264

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

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

US3042264

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	08:46 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 08:46
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3042264

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	09:42 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 09:42
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3042264

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3042264

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 13 JAN 2021

What was the treatment time? (00:00-23:59) 09:02 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 09:02

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

US3042264

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00-23:59)	08:22 (24 HR)
Collection date and time (derived)	13 JAN 2021 08:22

US3042264

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	13 JAN 2021
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Collection time (00:00 - 23:59)	08:31
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Collection Date and Time (derived)	13 JAN 2021 08:31
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US3042264

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3042264

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

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)	17 FEB 2021
Time of assessment (00:00-23:59)	08:12 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 08:12
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 FEB 2021
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 09:00
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3042264

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 FEB 2021

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

US3042264

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 17 FEB 2021

What was the treatment time? (00:00-23:59) 08:28 (24 HR)

Treatment Date and Time (derived) 17 FEB 2021 08:28

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

US3042264

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042264

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:37:48

Generated On: 09 Jun 2021 14:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042264

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:05 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 08:05
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042264

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

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.

US3042264

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	16 MAR 2021
Collection time (<i>00:00-23:59</i>)	08:20 (24 HR)
Collection date and time (derived)	16 MAR 2021 08:20

US3042264

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

AEID	USA-US052-2020-MRNA-1273-P30 1000013
Adverse event	3 RUPTURED DISCS IN LUMBAR SPINE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 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)	07 DEC 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 checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	28 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	346 of 2238

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

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	ADMITTED TO HOSPITAL FOR PAIN CONTROL AND TESTING. IMAGING WAS PERFORMED. NO SURGERY OR MED CHANGES.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

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

0

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

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

Yes ☒

No ☐

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

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Name of Medication SUCRALFATE

Prophylaxis Yes ☐
No ☒

Indication PEPTIC ULCER

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Name of Medication GEMFIBROZIE

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 600

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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US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

	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 2005	
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"/>

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL FOOT
NEUROPATHY-SENSORY

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL FOOT
NEUROPATHY-SENSORY

Dose per administration 600

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 (4)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

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 (6)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

	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 1993	
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) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

	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 1995
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) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

	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 1995
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 (10)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration .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 (10)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input 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)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (11)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Name of Medication GLIMEPIRIDE

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input 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)	UN UNK 2000	
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) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

Name of Medication HYDROCODONE/
ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 2.5/500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:36:48

Generated On: 09 Jun 2021 14:56:50

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:36:49

Generated On: 09 Jun 2021 14:56:50

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:56:50

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:56:50

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 ☐

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 17:31:06

Generated On: 09 Jun 2021 14:56:50

SAEID	USA-US052-2020-MRNA-1273-P301000013
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 17:31:06

Generated On: 09 Jun 2021 14:56:50

SAEID	USA-US052-2020-MRNA-1273-P301000013
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	29/OCT/2020 11:00
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

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 17:31:06

Generated On: 09 Jun 2021 14:56:50

SAEID	USA-US052-2020-MRNA-1273-P301000013
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	05/NOV/2020 11:18
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

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 17:31:06

Generated On: 09 Jun 2021 14:56:50

SAEID	USA-US052-2020-MRNA-1273-P301000013
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	09/NOV/2020 14:31
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

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 03 May 2021 17:31:06

Generated On: 09 Jun 2021 14:56:50

SAEID	USA-US052-2020-MRNA-1273-P301000013
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/NOV/2020 09:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Data signed: (b) (4) 03 May 2021 17:31:06

Generated On: 09 Jun 2021 14:56:50

SAEID	USA-US052-2020-MRNA-1273-P301000013
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	03/DEC/2020 19:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (6)

Data signed: (b) (4) 03 May 2021 17:31:06

Generated On: 09 Jun 2021 14:56:50

SAEID	USA-US052-2020-MRNA-1273-P301000013
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	10/DEC/2020 12:38
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

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (7)

Data signed: (b) (4) 03 May 2021 17:31:06

Generated On: 09 Jun 2021 14:56:50

SAEID	USA-US052-2020-MRNA-1273-P301000013
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	15/DEC/2020 16:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (8)

Data signed: (b) (4) 03 May 2021 17:31:06

Generated On: 09 Jun 2021 14:56:50

SAEID	USA-US052-2020-MRNA-1273-P301000013
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	DAVID
Investigator's Last Name	ENSZ
Site Address: Street	4802 SUNNYBROOK DRIVE
Site Address: City	SIOUX CITY
Site Address: State	IOWA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	28/APR/2021 08:52
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

US3042264 (Prod: Meridian Clinical Research)

US3042264

Form: Participant Creation

Generated On: 09 Jun 2021 14:56:50

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:02:12
User entered 'US3042264'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 20:49:40

US3042264

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:26
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Aug 2020 23:26:45
	(b) (4)	

US3042264

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:26
User entered '20 AUG 2020'	RWS_ENDPOINT	20 Aug 2020 20:49:41
	ENDPOINT (b) (4)	
	(b) (4)	

US3042264

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:26
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	20 Aug 2020 23:26:45
	(b) (4)	

US3042264

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'SCRN'	(b) (4), (b) (6) System	20 Aug 2020 23:26:45

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered (b) (6) 1951'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 20:49:42

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered '68'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:16
	(b) (4)	

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'YEARS'	(b) (4), (b) (6) System	20 Aug 2020 23:36:16

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '68'	(b) (4), (b) (6) System	20 Aug 2020 21:07:44

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered 'Male (M)'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:16
	(b) (4)	

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:16
	(b) (4)	

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered 'l'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:16
	(b) (4)	

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:16
	(b) (4)	

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:16
	(b) (4)	

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:16
	(b) (4)	

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:16
	(b) (4)	

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:16
	(b) (4)	

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered empty.	Rylea Gulick (b) (4)	20 Aug 2020 23:36:16
	(b) (4)	

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:16
	(b) (4)	

US3042264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:50

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:36
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:16
	(b) (4)	

US3042264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:50

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:47
User entered '20 Aug 2020'	Jessica Knight (b) (4)	20 Aug 2020 21:07:44
	(b) (4)	

US3042264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'Aug 2020'	(b) (4), (b) (6) System	20 Aug 2020 21:07:44

US3042264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '2020'	(b) (4), (b) (6) System	20 Aug 2020 21:07:44

US3042264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:50

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:47
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 21:07:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 21:07:50
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Jessica Knight (b) (4)	20 Aug 2020 21:07:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 21:07:44
User entered empty.	Jessica Knight (b) (4)	20 Aug 2020 21:07:44
	(b) (4)	

US3042264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:47
User entered 'Yes (Y)'	Jessica Knight (b) (4)	20 Aug 2020 21:07:44
	(b) (4)	

US3042264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:47
User entered empty.	Jessica Knight (b) (4)	20 Aug 2020 21:07:44
	(b) (4)	

US3042264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:50

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:47
User entered empty.	Jessica Knight (b) (4)	20 Aug 2020 21:07:44
	(b) (4)	

US3042264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:47
User entered 'No (N)'	Jessica Knight (b) (4)	20 Aug 2020 21:07:44
	(b) (4)	

US3042264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:47
User entered empty.	RWS_ENDPOINT	20 Aug 2020 20:49:41
	ENDPOINT (b) (4)	
	(b) (4)	

US3042264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'I'	(b) (4), (b) (6) System	20 Aug 2020 21:07:44

US3042264

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:01
User entered 'Yes (Y)'	Jessica Knight (b) (4)	20 Aug 2020 21:06:19
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:56:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:03:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:36:27

US3042264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User coded data point as SOC: Gastrointestinal disorders, HLGt: Gastrointestinal ulceration and perforation, HLT: Peptic ulcers and perforation, PT: Peptic ulcer, LLT: Peptic ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 23:37:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 23:37:30
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 23:36:47
User entered 'PEPTIC ULCER'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:37
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'UN UNK 2010'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:37
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:37
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:37
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered empty.	Rylea Gulick (b) (4)	20 Aug 2020 23:36:37
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:37
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'Jan 2010'	(b) (4), (b) (6) System	20 Aug 2020 23:36:37

US3042264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '2010'	(b) (4), (b) (6) System	20 Aug 2020 23:36:37

US3042264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:36:37

US3042264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:36:37

US3042264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
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)	20 Aug 2020 23:38:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 23:38:32
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 23:37:48
User entered 'HYPERLIPIDEMIA'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:51
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'UN UNK 2005'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:51
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:51
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:51
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered empty.	Rylea Gulick (b) (4)	20 Aug 2020 23:36:51
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:36:51
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'Jan 2005'	(b) (4), (b) (6) System	20 Aug 2020 23:36:51

US3042264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '2005'	(b) (4), (b) (6) System	20 Aug 2020 23:36:51

US3042264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:36:51

US3042264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:36:51

US3042264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:03:43
User closed query 'Per DM CLR: Please verify the type of the NEUROPATHY (e.g. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to Med History is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 08:39:24
User coded data point as SOC: Nervous system disorders, HLG: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Peripheral sensory neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 19:39:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 19:39:46
Data point term sent to Coder	System	09 Sep 2020 15:27:45
Query 'Per DM CLR: Please verify the type of the NEUROPATHY (e.g. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to Med History is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 15:27:34
Coding entries removed.	Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 15:27:31
User entered 'BILATERAL FOOT NEUROPATHY-SENSORY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	09 Sep 2020 15:27:31
User opened query 'Per DM CLR: Please verify the type of the NEUROPATHY (e.g. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to Med History is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 01:02:57
User coded data point as SOC: Nervous system disorders, HLG: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:38:32

US3042264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Aug 2020 23:38:32
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 23:37:50
User entered 'BILATERAL FOOT NEUROPATHY'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:20
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'UN UNK 2010'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:20
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:20
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:20
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered empty.	Rylea Gulick (b) (4)	20 Aug 2020 23:37:20
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:20
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'Jan 2010'	(b) (4), (b) (6) System	20 Aug 2020 23:37:20

US3042264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '2010'	(b) (4), (b) (6) System	20 Aug 2020 23:37:20

US3042264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:37:20

US3042264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:37:20

US3042264

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:03:43
User coded data point as SOC: Gastrointestinal disorders, HLGt: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:38:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:38:32
Data point term sent to Coder	System	20 Aug 2020 23:37:48
User entered 'ACID REFLUX'	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:37:27

US3042264

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'UN UNK 2010'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:27
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:37:27

US3042264

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:27
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered empty.	Rylea Gulick (b) (4)	20 Aug 2020 23:37:27
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:27
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'Jan 2010'	(b) (4), (b) (6) System	20 Aug 2020 23:37:27

US3042264

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '2010'	(b) (4), (b) (6) System	20 Aug 2020 23:37:27

US3042264

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:37:27

US3042264

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:37:27

US3042264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:56:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:03:43
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:38:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:38:32
Data point term sent to Coder	System	20 Aug 2020 23:37:50
User entered 'DIABETES TYPE 2'	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:37:40

US3042264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'UN UNK 1993'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:40
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:40
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:56:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:40
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered empty.	Rylea Gulick (b) (4)	20 Aug 2020 23:37:40
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:56:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:40
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'Jan 1993'	(b) (4), (b) (6) System	20 Aug 2020 23:37:40

US3042264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '1993'	(b) (4), (b) (6) System	20 Aug 2020 23:37:40

US3042264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:37:40

US3042264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:37:40

US3042264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:56:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
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)	20 Aug 2020 23:39:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:39:20
Data point term sent to Coder	System	20 Aug 2020 23:38:51
User entered 'HYPERTENSION'	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:37:51

US3042264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'UN UNK 1995'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:51
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:51
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:56:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:51
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered empty.	Rylea Gulick (b) (4)	20 Aug 2020 23:37:51
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:56:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:37:51
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'Jan 1995'	(b) (4), (b) (6) System	20 Aug 2020 23:37:51

US3042264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '1995'	(b) (4), (b) (6) System	20 Aug 2020 23:37:51

US3042264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:37:51

US3042264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:37:51

US3042264

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:56:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:03:43
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) (b) (4)	20 Aug 2020 23:39:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:39:20
Data point term sent to Coder	System	20 Aug 2020 23:38:51
User entered 'BENIGN PROSTATIC HYPERPLASIA'	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:38:08

US3042264

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'UN Nov 2015'	Rylea Gulick (b) (4)	20 Aug 2020 23:38:08
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:38:08
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:56:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Aug 2020 23:38:08
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered empty.	Rylea Gulick (b) (4)	20 Aug 2020 23:38:08
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:56:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:38:08

US3042264

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'Nov 2015'	(b) (4), (b) (6) System	20 Aug 2020 23:38:08

US3042264

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '2015'	(b) (4), (b) (6) System	20 Aug 2020 23:38:08

US3042264

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:38:08

US3042264

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:38:08

US3042264

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:56:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:03:43
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (e.g. Rheumatoid, Osteoarthritis etc.) and the location. If this is RHEUMATOID ARTHRITIS, note that treatment is expected for this condition. Please reconcile with Con Med and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 07:01:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 19:21:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 19:21:41
Query 'Per DM CLR: Please specify the type of ARTHRITIS (e.g. Rheumatoid, Osteoarthritis etc.) and the location. If this is RHEUMATOID ARTHRITIS, note that treatment is expected for this condition. Please reconcile with Con Med and Med History eCRFs as appropriate.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 19:20:47
Data point term sent to Coder	System	10 Sep 2020 19:20:46
Coding entries removed.	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 19:20:38
User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 19:20:38
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (e.g. Rheumatoid, Osteoarthritis etc.) and the location. If this is RHEUMATOID ARTHRITIS, note that treatment is expected for this condition. Please reconcile with Con Med and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 01:03:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:40:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:40:22

US3042264

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:56:50

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	20 Aug 2020 23:39:51
User entered 'ARTHRITIS'	Rylea Gulick (b) (4)	20 Aug 2020 23:39:29
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'UN UNK 2015'	Rylea Gulick (b) (4)	20 Aug 2020 23:39:29
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:56:50

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:03:43
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	20 Aug 2020 23:39:32
User entered '0' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:39:32
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	20 Aug 2020 23:39:29
User entered '1'	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:39:29

US3042264

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:56:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 23:39:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 23:39:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	20 Aug 2020 23:39:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 23:39:29
User entered empty.	Rylea Gulick (b) (4)	20 Aug 2020 23:39:29
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered empty.	Rylea Gulick (b) (4)	20 Aug 2020 23:39:29
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:56:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:39:29

US3042264

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'Jan 2015'	(b) (4), (b) (6) System	20 Aug 2020 23:39:29

US3042264

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '2015'	(b) (4), (b) (6) System	20 Aug 2020 23:39:29

US3042264

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:39:29

US3042264

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 23:39:29

US3042264

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:56:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis A, LLT: Hepatitis A - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:40:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:40:21
Data point term sent to Coder	System	20 Aug 2020 23:39:52
User entered 'HEPATITIS A'	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:39:46

US3042264

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'UN UNK 1991'	Rylea Gulick (b) (4)	20 Aug 2020 23:39:46
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:39:46

US3042264

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:56:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Aug 2020 23:39:46
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered 'UN UNK 1991'	Rylea Gulick (b) (4)	20 Aug 2020 23:39:46
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:56:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:43
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:39:46
	(b) (4)	

US3042264

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'Jan 1991'	(b) (4), (b) (6) System	20 Aug 2020 23:39:46

US3042264

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '1991'	(b) (4), (b) (6) System	20 Aug 2020 23:39:46

US3042264

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'Jan 1991'	(b) (4), (b) (6) System	20 Aug 2020 23:39:46

US3042264

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '1991'	(b) (4), (b) (6) System	20 Aug 2020 23:39:46

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:58
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Aug 2020 23:40:20
	(b) (4)	

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:58
User entered '20 Aug 2020'	Rylea Gulick (b) (4)	20 Aug 2020 23:40:20
	(b) (4)	

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:58
User entered '15:05'	Rylea Gulick (b) (4)	20 Aug 2020 23:40:20
	(b) (4)	

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered '20 Aug 2020 15:05'	(b) (4), (b) (6) System	20 Aug 2020 23:40:20

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:58
User entered '185.4' cm	Rylea Gulick (b) (4)	20 Aug 2020 23:40:20
	(b) (4)	
DataPoint set to visible.	System	20 Aug 2020 21:07:44

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:58
User entered '109.5' kg	Rylea Gulick (b) (4)	20 Aug 2020 23:40:20
	(b) (4)	
DataPoint set to visible.	System	20 Aug 2020 21:07:44

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
Amendment Manager: User entered '31.85625'	(b) (4), (b) (6)	
User entered '31.9'	System	17 Sep 2020 00:17:12
DataPoint set to visible.	System	20 Aug 2020 23:40:20
	System	20 Aug 2020 21:07:44

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	20 Aug 2020 23:40:20
DataPoint set to visible.	System	20 Aug 2020 21:07:44

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:03:58
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 07:27:38
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:40:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 14:40:24
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:37:33
User entered '36.9' C	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:40:20

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:58
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4)	08 Oct 2020 14:40:24
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	20 Aug 2020 23:40:20
	(b) (4)	

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:58
User entered empty.	Rylea Gulick (b) (4)	20 Aug 2020 23:40:20
	(b) (4)	

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:58
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:40:24
change Data Entry Error	(b) (4)	
User entered '72'	Rylea Gulick (b) (4)	20 Aug 2020 23:40:20
	(b) (4)	

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'bpm'	(b) (4), (b) (6) System	20 Aug 2020 23:40:20

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:58
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:40:24
change Data Entry Error	(b) (4)	
User entered '16'	Rylea Gulick (b) (4)	20 Aug 2020 23:40:20
	(b) (4)	

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'breaths/min'	(b) (4), (b) (6) System	20 Aug 2020 23:40:20

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:58
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:40:24
change Data Entry Error	(b) (4)	
User entered '143'	Rylea Gulick (b) (4)	20 Aug 2020 23:40:20
	(b) (4)	

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 23:40:20

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:58
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	08 Oct 2020 14:40:24
change Data Entry Error	(b) (4)	
User entered '71'	Rylea Gulick (b) (4)	20 Aug 2020 23:40:20
	(b) (4)	

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 23:40:20

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 06:03:16

US3042264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 06:03:16

US3042264

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:19
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Aug 2020 23:58:24
	(b) (4)	

US3042264

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:19
User entered '20 Aug 2020'	Rylea Gulick (b) (4)	20 Aug 2020 23:58:24
	(b) (4)	

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Aug 2020 23:59:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[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)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

[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)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'No (N)'	Rylea Gulick (b) (4)	20 Aug 2020 23:59:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	20 Aug 2020 23:59:04
	(b) (4)	

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'OUT IN COMMUNITY FREQUENTLY WITHOUT MASK'	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:59:04
	(b) (4)	

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

[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)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered '0'	Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered 'l'	(b) (4) Rylea Gulick (b) (4) (b) (4)	20 Aug 2020 23:59:04

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	20 Aug 2020 23:59:04
	(b) (4)	

US3042264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:03:16
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:31
User entered empty.	Rylea Gulick (b) (4)	20 Aug 2020 23:59:04
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:05:33
User entered 'Yes (Y)'	Jessica Knight (b) (4)	20 Aug 2020 21:06:48
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:05:33
User entered '20 Aug 2020'	Jessica Knight (b) (4)	20 Aug 2020 21:06:48
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:05:33
User entered 'Clinic (Clinic)'	Jessica Knight (b) (4)	20 Aug 2020 21:06:48
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered 'VISIT1'	(b) (4), (b) (6) System	20 Aug 2020 21:06:48

US3042264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:05:44
User entered '20 AUG 2020'	RWS_ENDPOINT	20 Aug 2020 20:54:28
	ENDPOINT (b) (4)	
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:50

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:05:44
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 06:03:28
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 06:03:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 20:54:28
User entered '187130' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 20:54:28

US3042264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:05:44
User entered '>=65 years (3)'	RWS_ENDPOINT	20 Aug 2020 20:54:28
	ENDPOINT (b) (4)	
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:05:44
User entered 'No (N)'	(b) (4) Jessica Knight (b) (4) (b) (4)	20 Aug 2020 21:07:25

US3042264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:05:44
User entered 'No (N)'	(b) (4) Jessica Knight (b) (4) (b) (4)	20 Aug 2020 21:07:25

US3042264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:05:44
User entered 'No (N)'	(b) (4)	
	Jessica Knight (b) (4)	20 Aug 2020 21:07:25
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:05:44
User entered 'Yes (Y)'	(b) (4) Jessica Knight (b) (4) (b) (4)	20 Aug 2020 21:07:25

US3042264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:50

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:05:44
User entered 'No (N)'	Jessica Knight (b) (4)	20 Aug 2020 21:07:25
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:50

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:05:44
	(b) (4), (b) (6)	
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:30:41
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'ENTRY UPDATED ' (Site from DM).	Rylea Gulick (b) (4)	29 Oct 2020 17:50:34
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	29 Oct 2020 17:50:31
	(b) (4)	
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:02:17
	(b) (4), (b) (6)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:36
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:52:24

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:10:31
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 07:25:16
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:49:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:48:58
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 06:57:40
User entered '185.4' cm	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:20:19

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:48:58
	(b) (4)	
User entered '109.5' kg	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:10:31
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 07:25:16
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:49:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:48:58
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 06:57:40
User entered '185.4' cm	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:20:19

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:48:58
change Data Entry Error	(b) (4)	
User entered '109.5' kg	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:20:19

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 00:27:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 00:27:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 00:20:19
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '20 Aug 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '15:05' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered '20 Aug 2020 15:05'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:27:00
User entered empty.	System	21 Aug 2020 00:20:19

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '36.9' C reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '72' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered 'bpm'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:27:00
User entered empty.	System	21 Aug 2020 00:20:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '16' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	21 Aug 2020 00:27:00
User entered empty.	System	21 Aug 2020 00:20:19

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '143' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered 'mmHg'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:27:00
User entered empty.	System	21 Aug 2020 00:20:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '71' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered 'mmHg'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:27:00
User entered empty.	System	21 Aug 2020 00:20:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:10:31
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 07:25:16
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:49:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 19:48:58
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Kindly remove the units as well. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 06:57:40
User entered '185.4' cm	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:20:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:48:58
	(b) (4)	
User entered '109.5' kg	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:20:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 00:27:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 00:27:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 00:20:19
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '20 Aug 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:10:31
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'PER PROTOCOL, SUBJECT ONLY NEEDS TO WAIT 30 MINUTES AFTER VACCINATION BEFORE POST DOSE VITALS ARE TAKEN' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:27:19
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		21 Aug 2020 00:27:00
User entered '16:36' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:27:00
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:20:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered '20 Aug 2020 16:36'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:27:00
User entered empty.	System	21 Aug 2020 00:20:19

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '36.8' C reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '72' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered 'bpm'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:27:00
User entered empty.	System	21 Aug 2020 00:20:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '14' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	21 Aug 2020 00:27:00
User entered empty.	System	21 Aug 2020 00:20:19

US3042264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '120' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered 'mmHg'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:27:00
User entered empty.	System	21 Aug 2020 00:20:19

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:31
User entered '88' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:00
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:20:19
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered 'mmHg'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:27:00
User entered empty.	System	21 Aug 2020 00:20:19

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:18:04
User entered 'Yes (Y)'		
	Rylea Gulick (b) (4)	21 Aug 2020 00:27:24
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:18:04
User entered '20 Aug 2020'		
	Rylea Gulick (b) (4)	21 Aug 2020 00:27:24
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:12
User entered 'Yes (Y)'	Jessica Knight (b) (4)	20 Aug 2020 21:10:15
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:12
User entered empty.	Jessica Knight (b) (4)	20 Aug 2020 21:10:15
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:18:12
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	20 Aug 2020 21:10:15

US3042264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:18:12
User entered '20 Aug 2020'		
	Jessica Knight (b) (4)	20 Aug 2020 21:10:15
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:12
User entered '16:01'	Jessica Knight (b) (4)	20 Aug 2020 21:10:15
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered '20 Aug 2020 16:01'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:18:12
User entered 'Left Arm (LEFT ARM)'	(b) (4)	
	Jessica Knight (b) (4)	20 Aug 2020 21:10:15
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:12
User entered 'ONCE'	System	20 Aug 2020 21:10:15

US3042264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:18:27
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:27:32

US3042264

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:18:27
User entered '20 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:27:32

US3042264

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:18:27
User entered '15:40'		
	Rylea Gulick (b) (4)	21 Aug 2020 00:27:32
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered '20 Aug 2020 15:40'	(b) (4), (b) (6) System	21 Aug 2020 00:27:32

US3042264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:56:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:18:42
User entered '20 Aug 2020'		
	Rylea Gulick (b) (4)	21 Aug 2020 00:27:48
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Rylea Gulick (b) (4)	21 Aug 2020 00:27:48

US3042264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:42
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Aug 2020 00:27:48
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:42
User entered '15:27'	Rylea Gulick (b) (4)	21 Aug 2020 00:27:48
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered '20 Aug 2020 15:27'	(b) (4), (b) (6) System	21 Aug 2020 00:27:48

US3042264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:27:48

US3042264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 16:18:42
User entered 'No (N)'		
	Rylea Gulick (b) (4)	21 Aug 2020 00:27:48
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:42
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:27:48
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 00:27:48

US3042264

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 00:27:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 00:27:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	21 Aug 2020 00:27:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 00:27:50
User entered empty.	Rylea Gulick (b) (4)	21 Aug 2020 00:27:50
	(b) (4)	

US3042264

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:58:49
User entered 'I'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:27:53
User entered empty.	System	21 Aug 2020 00:27:50

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:35:47', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '88178bed-fedb-4ef1-8bf3-043d1b66060f'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	20 Aug 2020 21:36:26

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:36:04', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '88178bed-fedb-4ef1-8bf3-043d1b66060f' User entered '98.2'	(b) (4), (b) (6) System	20 Aug 2020 21:36:26
	System	20 Aug 2020 21:36:26

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:36:11', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '88178bed-fedb-4ef1-8bf3-043d1b66060f'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 21:36:26

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:36:24', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '88178bed-fedb-4ef1-8bf3-043d1b66060f'	(b) (4), (b) (6) System	20 Aug 2020 21:36:26
User entered '20 Aug 2020 16:36'	System	20 Aug 2020 21:36:26

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '20 Aug 2020 16:21'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '20 Aug 2020 18:51'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:50:23', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5e8b5456-25b3-46e2-9b0b-151106d3bd67'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:50:38
User entered 'No (N)'	System	21 Aug 2020 00:50:38

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:50:29', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5e8b5456-25b3-46e2-9b0b-151106d3bd67'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:50:38
User entered 'No (N)'	System	21 Aug 2020 00:50:38

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:50:36', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5e8b5456-25b3-46e2-9b0b-151106d3bd67'	(b) (4), (b) (6) System	21 Aug 2020 00:50:38
User entered '20 Aug 2020 19:50'	System	21 Aug 2020 00:50:38

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '20 Aug 2020 19:46'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 2'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:12:40', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e803c982-5882-4a47-930c-3bafb3515fa6'	(b) (4), (b) (6)	
	System	21 Aug 2020 17:14:00
User entered 'Yes (Y)'	System	21 Aug 2020 17:14:00

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:13:46', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e803c982-5882-4a47-930c-3bafb3515fa6' User entered '97.7'	(b) (4), (b) (6) System	21 Aug 2020 17:14:00
	System	21 Aug 2020 17:14:00

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:13:51', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e803c982-5882-4a47-930c-3bafb3515fa6'	(b) (4), (b) (6)	
	System	21 Aug 2020 17:14:00
User entered 'No (N)'	System	21 Aug 2020 17:14:00

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:13:57', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e803c982-5882-4a47-930c-3bafb3515fa6'	(b) (4), (b) (6) System	21 Aug 2020 17:14:00
User entered '21 Aug 2020 12:13'	System	21 Aug 2020 17:14:00

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 3'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:01:11', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b76bbb7b-d03e-4f59-9fa3-547066a56602'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	22 Aug 2020 17:02:38

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:02:12', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b76bbb7b-d03e-4f59-9fa3-547066a56602'	(b) (4), (b) (6)	
User entered '98.2'	System	22 Aug 2020 17:02:38

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:02:21', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b76bbb7b-d03e-4f59-9fa3-547066a56602'	(b) (4), (b) (6)	
	System	22 Aug 2020 17:02:38
User entered 'No (N)'	System	22 Aug 2020 17:02:38

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:02:32', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b76bbb7b-d03e-4f59-9fa3-547066a56602'	(b) (4), (b) (6) System	22 Aug 2020 17:02:38
User entered '22 Aug 2020 12:02'	System	22 Aug 2020 17:02:38

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 4'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:00:34', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f413ba54-f713-40c6-813e-b03c7596f433'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:01:00
User entered 'Yes (Y)'	System	23 Aug 2020 17:01:00

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:00:40', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f413ba54-f713-40c6-813e-b03c7596f433'	(b) (4), (b) (6)	
User entered '98.2'	System	23 Aug 2020 17:01:00

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:00:46', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f413ba54-f713-40c6-813e-b03c7596f433'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:01:00
User entered 'No (N)'	System	23 Aug 2020 17:01:00

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:00:54', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f413ba54-f713-40c6-813e-b03c7596f433'	(b) (4), (b) (6) System	23 Aug 2020 17:01:00
User entered '23 Aug 2020 12:00'	System	23 Aug 2020 17:01:00

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 5'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:08:24', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '06c0d9ec-d07a-4230-bd04-aaa034e54295'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	24 Aug 2020 19:08:44

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:08:30', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '06c0d9ec-d07a-4230-bd04-aaa034e54295'	(b) (4), (b) (6)	
User entered '97.7'	System	24 Aug 2020 19:08:44

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:08:36', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '06c0d9ec-d07a-4230-bd04-aaa034e54295'	(b) (4), (b) (6)	
User entered 'No (N)'	System	24 Aug 2020 19:08:44

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:08:40', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '06c0d9ec-d07a-4230-bd04-aaa034e54295'	(b) (4), (b) (6)	
User entered '24 Aug 2020 14:08'	System	24 Aug 2020 19:08:44

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 6'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:01:47', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'fd3026b5-54ff-41b1-b815-d371503d7dc5'	(b) (4), (b) (6)	
	System	25 Aug 2020 17:02:10
User entered 'Yes (Y)'	System	25 Aug 2020 17:02:10

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:01:54', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'fd3026b5-54ff-41b1-b815-d371503d7dc5'	(b) (4), (b) (6)	25 Aug 2020 17:02:10
User entered '97.2'	System	25 Aug 2020 17:02:10

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:01:59', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'fd3026b5-54ff-41b1-b815-d371503d7dc5'	(b) (4), (b) (6)	
	System	25 Aug 2020 17:02:10
User entered 'No (N)'	System	25 Aug 2020 17:02:10

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:04', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'fd3026b5-54ff-41b1-b815-d371503d7dc5'	(b) (4), (b) (6)	25 Aug 2020 17:02:10
User entered '25 Aug 2020 12:02'	System	25 Aug 2020 17:02:10

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 7'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:02', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'a1f006f4-40fd-4ca6-bd2e-ceebdea2e36d'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	26 Aug 2020 17:01:41

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:10', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'a1f006f4-40fd-4ca6-bd2e-ceedea2e36d'	(b) (4), (b) (6)	
User entered '98.0'	System	26 Aug 2020 17:01:41

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:14', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'a1f006f4-40fd-4ca6-bd2e-ceedea2e36d'	(b) (4), (b) (6)	
User entered 'No (N)'	System	26 Aug 2020 17:01:41

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:18', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'a1f006f4-40fd-4ca6-bd2e-ceedea2e36d'	(b) (4), (b) (6)	
User entered '26 Aug 2020 12:01'	System	26 Aug 2020 17:01:41

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:36:38', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a5aaf7-6da1-454a-a007-0a14b8614c94'	(b) (4), (b) (6)	
	System	20 Aug 2020 21:37:10
User entered 'None (1)'	System	20 Aug 2020 21:37:10

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:36:47', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a5aaf7-6da1-454a-a007-0a14b8614c94'	(b) (4), (b) (6) System	20 Aug 2020 21:37:10
User entered 'No (N)'	System	20 Aug 2020 21:37:10

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:36:54', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a5aaf7-6da1-454a-a007-0a14b8614c94'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 21:37:10

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:37:04', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a5aaf7-6da1-454a-a007-0a14b8614c94'	(b) (4), (b) (6)	20 Aug 2020 21:37:10
User entered 'None (1)'	System	20 Aug 2020 21:37:10

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:37:08', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a5aaf7-6da1-454a-a007-0a14b8614c94'	(b) (4), (b) (6)	
	System	20 Aug 2020 21:37:10
User entered '20 Aug 2020 16:37'	System	20 Aug 2020 21:37:10

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '20 Aug 2020 16:21'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '20 Aug 2020 18:51'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:50:45', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'ecb67e73-06fd-4d6f-b1d5-15ec6a855596'	(b) (4), (b) (6) System	21 Aug 2020 00:51:08
User entered 'None (1)'	System	21 Aug 2020 00:51:08

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:50:49', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'ecb67e73-06fd-4d6f-b1d5-15ec6a855596'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:51:08
User entered 'No (N)'	System	21 Aug 2020 00:51:08

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:50:52', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'ecb67e73-06fd-4d6f-b1d5-15ec6a855596'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:51:08
User entered 'No (N)'	System	21 Aug 2020 00:51:08

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:50:59', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'ecb67e73-06fd-4d6f-b1d5-15ec6a855596'	(b) (4), (b) (6)	21 Aug 2020 00:51:08
User entered 'None (1)'	System	21 Aug 2020 00:51:08

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:51:03', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'ecb67e73-06fd-4d6f-b1d5-15ec6a855596'	(b) (4), (b) (6) System	21 Aug 2020 00:51:08
User entered '20 Aug 2020 19:51'	System	21 Aug 2020 00:51:08

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '20 Aug 2020 19:46'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 2'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:14:17', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'eb86f0fa-922b-4bd3-8924-63280fa660f9'	(b) (4), (b) (6) System	21 Aug 2020 17:14:46
User entered 'None (1)'	System	21 Aug 2020 17:14:46

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:14:22', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'eb86f0fa-922b-4bd3-8924-63280fa660f9'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Aug 2020 17:14:46

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:14:25', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'eb86f0fa-922b-4bd3-8924-63280fa660f9'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Aug 2020 17:14:46

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:14:34', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'eb86f0fa-922b-4bd3-8924-63280fa660f9'	(b) (4), (b) (6) System	21 Aug 2020 17:14:46
User entered 'None (1)'	System	21 Aug 2020 17:14:46

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:14:38', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'eb86f0fa-922b-4bd3-8924-63280fa660f9'	(b) (4), (b) (6)	
	System	21 Aug 2020 17:14:46
User entered '21 Aug 2020 12:14'	System	21 Aug 2020 17:14:46

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 3'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:02:41', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'edeae887-534e-47be-b994-4040770af9fc'	(b) (4), (b) (6) System	22 Aug 2020 17:02:59
User entered 'None (1)'	System	22 Aug 2020 17:02:59

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:02:44', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'edeae887-534e-47be-b994-4040770af9fc'	(b) (4), (b) (6) System	22 Aug 2020 17:02:59
User entered 'No (N)'	System	22 Aug 2020 17:02:59

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:02:47', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'edeae887-534e-47be-b994-4040770af9fc'	(b) (4), (b) (6)	
User entered 'No (N)'	System	22 Aug 2020 17:02:59

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:02:51', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'edeae887-534e-47be-b994-4040770af9fc'	(b) (4), (b) (6) System	22 Aug 2020 17:02:59
User entered 'None (1)'	System	22 Aug 2020 17:02:59

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:02:55', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'edeae887-534e-47be-b994-4040770af9fc'	(b) (4), (b) (6) System	22 Aug 2020 17:02:59
User entered '22 Aug 2020 12:02'	System	22 Aug 2020 17:02:59

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 4'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:05', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9e654032-2f76-4b43-8d0b-1f9eb63fc4db'	(b) (4), (b) (6)	23 Aug 2020 17:01:27
User entered 'None (1)'	System	23 Aug 2020 17:01:27

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:10', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9e654032-2f76-4b43-8d0b-1f9eb63fc4db'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:01:27
User entered 'No (N)'	System	23 Aug 2020 17:01:27

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:13', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9e654032-2f76-4b43-8d0b-1f9eb63fc4db'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:01:27
User entered 'No (N)'	System	23 Aug 2020 17:01:27

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:17', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9e654032-2f76-4b43-8d0b-1f9eb63fc4db'	(b) (4), (b) (6) System	23 Aug 2020 17:01:27
User entered 'None (1)'	System	23 Aug 2020 17:01:27

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:24', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9e654032-2f76-4b43-8d0b-1f9eb63fc4db'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:01:27
User entered '23 Aug 2020 12:01'	System	23 Aug 2020 17:01:27

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 5'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:08:45', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0da735ac-6506-4cba-9f95-0d79069d8b82'	(b) (4), (b) (6)	
	System	24 Aug 2020 19:09:03
User entered 'None (1)'	System	24 Aug 2020 19:09:03

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:08:49', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0da735ac-6506-4cba-9f95-0d79069d8b82'	(b) (4), (b) (6)	
User entered 'No (N)'	System	24 Aug 2020 19:09:03

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:08:52', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0da735ac-6506-4cba-9f95-0d79069d8b82'	(b) (4), (b) (6)	
User entered 'No (N)'	System	24 Aug 2020 19:09:03

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:08:56', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0da735ac-6506-4cba-9f95-0d79069d8b82'	(b) (4), (b) (6)	
	System	24 Aug 2020 19:09:03
User entered 'None (1)'	System	24 Aug 2020 19:09:03

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:09:00', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0da735ac-6506-4cba-9f95-0d79069d8b82'	(b) (4), (b) (6) System	24 Aug 2020 19:09:03
User entered '24 Aug 2020 14:09'	System	24 Aug 2020 19:09:03

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 6'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:08', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '032f2db4-523e-4605-9f3e-f4fefa37504'	(b) (4), (b) (6)	25 Aug 2020 17:02:24
User entered 'None (1)'	System	25 Aug 2020 17:02:24

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:12', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '032f2db4-523e-4605-9f3e-f4fefea37504'	(b) (4), (b) (6)	
User entered 'No (N)'	System	25 Aug 2020 17:02:24

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:14', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '032f2db4-523e-4605-9f3e-f4feea37504'	(b) (4), (b) (6)	
User entered 'No (N)'	System	25 Aug 2020 17:02:24

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:17', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '032f2db4-523e-4605-9f3e-f4fefa37504'	(b) (4), (b) (6)	25 Aug 2020 17:02:24
User entered 'None (1)'	System	25 Aug 2020 17:02:24

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:21', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '032f2db4-523e-4605-9f3e-f4feffa37504'	(b) (4), (b) (6)	
	System	25 Aug 2020 17:02:24
User entered '25 Aug 2020 12:02'	System	25 Aug 2020 17:02:24

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 7'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:23', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '79b8ed04-39af-4ea8-95df-478930adaafd'	(b) (4), (b) (6) System	26 Aug 2020 17:01:54
User entered 'None (1)'	System	26 Aug 2020 17:01:54

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:27', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '79b8ed04-39af-4ea8-95df-478930adaafd'	(b) (4), (b) (6)	
User entered 'No (N)'	System	26 Aug 2020 17:01:54

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:29', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '79b8ed04-39af-4ea8-95df-478930adaafd'	(b) (4), (b) (6)	
User entered 'No (N)'	System	26 Aug 2020 17:01:54

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:31', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '79b8ed04-39af-4ea8-95df-478930adaafd'	(b) (4), (b) (6)	
	System	26 Aug 2020 17:01:54
User entered 'None (1)'	System	26 Aug 2020 17:01:54

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:34', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '79b8ed04-39af-4ea8-95df-478930adaafd'	(b) (4), (b) (6)	
User entered '26 Aug 2020 12:01'	System	26 Aug 2020 17:01:54

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:37:36', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '1692b3dd-c209-437b-8401-feb6bb9f4d99'	(b) (4), (b) (6)	
	System	20 Aug 2020 21:38:06
User entered 'None (0)'	System	20 Aug 2020 21:38:06

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:37:39', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '1692b3dd-c209-437b-8401-feb6bb9f4d99'	(b) (4), (b) (6) System	20 Aug 2020 21:38:06
User entered 'None (0)'	System	20 Aug 2020 21:38:06

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:37:43', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '1692b3dd-c209-437b-8401-feb6bb9f4d99'	(b) (4), (b) (6) System	20 Aug 2020 21:38:06
User entered 'None (0)'	System	20 Aug 2020 21:38:06

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:37:47', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '1692b3dd-c209-437b-8401-feb6bb9f4d99'	(b) (4), (b) (6)	
User entered 'None (0)'	System	20 Aug 2020 21:38:06

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:37:50', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '1692b3dd-c209-437b-8401-feb6bb9f4d99'	(b) (4), (b) (6) System	20 Aug 2020 21:38:06
User entered 'None (0)'	System	20 Aug 2020 21:38:06

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:37:54', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '1692b3dd-c209-437b-8401-feb6bb9f4d99'	(b) (4), (b) (6)	
	System	20 Aug 2020 21:38:06
User entered 'None (0)'	System	20 Aug 2020 21:38:06

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:37:59', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '1692b3dd-c209-437b-8401-feb6bb9f4d99'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 21:38:06

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T16:38:02', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '1692b3dd-c209-437b-8401-feb6bb9f4d99'	(b) (4), (b) (6) System	20 Aug 2020 21:38:06
User entered '20 Aug 2020 16:38'	System	20 Aug 2020 21:38:06

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '20 Aug 2020 16:21'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '20 Aug 2020 18:51'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:51:20', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '191a372e-daab-463f-9de8-5f4e72237604'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:51:55
User entered 'None (0)'	System	21 Aug 2020 00:51:55

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:51:24', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '191a372e-daab-463f-9de8-5f4e72237604'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 00:51:55

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:51:28', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '191a372e-daab-463f-9de8-5f4e72237604'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 00:51:55

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:51:31', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '191a372e-daab-463f-9de8-5f4e72237604'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 00:51:55

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:51:34', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '191a372e-daab-463f-9de8-5f4e72237604'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 00:51:55

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:51:38', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '191a372e-daab-463f-9de8-5f4e72237604'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:51:55
User entered 'None (0)'	System	21 Aug 2020 00:51:55

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:51:44', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '191a372e-daab-463f-9de8-5f4e72237604'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:51:55
User entered 'No (N)'	System	21 Aug 2020 00:51:55

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-20T19:51:52', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '191a372e-daab-463f-9de8-5f4e72237604'	(b) (4), (b) (6) System	21 Aug 2020 00:51:55
User entered '20 Aug 2020 19:51'	System	21 Aug 2020 00:51:55

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '20 Aug 2020 19:46'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 2'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:14:46', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '6f9f537c-77d6-4e9f-a148-f310ed308b54'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 17:15:40

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:14:51', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '6f9f537c-77d6-4e9f-a148-f310ed308b54'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 17:15:40

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:14:54', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '6f9f537c-77d6-4e9f-a148-f310ed308b54'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 17:15:40

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:14:56', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '6f9f537c-77d6-4e9f-a148-f310ed308b54'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 17:15:40

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:14:59', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '6f9f537c-77d6-4e9f-a148-f310ed308b54'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 17:15:40

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:15:02', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '6f9f537c-77d6-4e9f-a148-f310ed308b54'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 17:15:40

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:15:09', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '6f9f537c-77d6-4e9f-a148-f310ed308b54'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Aug 2020 17:15:40

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-21T12:15:12', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '6f9f537c-77d6-4e9f-a148-f310ed308b54'	(b) (4), (b) (6) System	21 Aug 2020 17:15:40
User entered '21 Aug 2020 12:15'	System	21 Aug 2020 17:15:40

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 3'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:03:09', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9610ae74-c017-4afc-9509-5ee14ec3b2d8'	(b) (4), (b) (6)	
User entered 'None (0)'	System	22 Aug 2020 17:03:41

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:03:11', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9610ae74-c017-4afc-9509-5ee14ec3b2d8'	(b) (4), (b) (6) System	22 Aug 2020 17:03:41
User entered 'None (0)'	System	22 Aug 2020 17:03:41

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:03:23', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9610ae74-c017-4afc-9509-5ee14ec3b2d8'	(b) (4), (b) (6)	
User entered 'None (0)'	System	22 Aug 2020 17:03:41

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:03:26', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9610ae74-c017-4afc-9509-5ee14ec3b2d8'	(b) (4), (b) (6)	
User entered 'None (0)'	System	22 Aug 2020 17:03:41

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:03:29', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9610ae74-c017-4afc-9509-5ee14ec3b2d8'	(b) (4), (b) (6) System	22 Aug 2020 17:03:41
User entered 'None (0)'	System	22 Aug 2020 17:03:41

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:03:31', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9610ae74-c017-4afc-9509-5ee14ec3b2d8'	(b) (4), (b) (6) System	22 Aug 2020 17:03:41
User entered 'None (0)'	System	22 Aug 2020 17:03:41

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:03:34', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9610ae74-c017-4afc-9509-5ee14ec3b2d8'	(b) (4), (b) (6) System	22 Aug 2020 17:03:41
User entered 'No (N)'	System	22 Aug 2020 17:03:41

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-22T12:03:38', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9610ae74-c017-4afc-9509-5ee14ec3b2d8'	(b) (4), (b) (6) System	22 Aug 2020 17:03:41
User entered '22 Aug 2020 12:03'	System	22 Aug 2020 17:03:41

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 4'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:29', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '61052662-ffaa-43c7-bbd9-fe30c69c76f8'	(b) (4), (b) (6)	23 Aug 2020 17:01:53
User entered 'None (0)'	System	23 Aug 2020 17:01:53

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:32', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '61052662-ffaa-43c7-bbd9-fe30c69c76f8'	(b) (4), (b) (6) System	23 Aug 2020 17:01:53
User entered 'None (0)'	System	23 Aug 2020 17:01:53

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:34', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '61052662-ffaa-43c7-bbd9-fe30c69c76f8'	(b) (4), (b) (6) System	23 Aug 2020 17:01:53
User entered 'None (0)'	System	23 Aug 2020 17:01:53

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:37', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '61052662-ffaa-43c7-bbd9-fe30c69c76f8'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:01:53
User entered 'None (0)'	System	23 Aug 2020 17:01:53

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:39', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '61052662-ffaa-43c7-bbd9-fe30c69c76f8'	(b) (4), (b) (6) System	23 Aug 2020 17:01:53
User entered 'None (0)'	System	23 Aug 2020 17:01:53

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:42', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '61052662-ffaa-43c7-bbd9-fe30c69c76f8'	(b) (4), (b) (6) System	23 Aug 2020 17:01:53
User entered 'None (0)'	System	23 Aug 2020 17:01:53

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:45', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '61052662-ffaa-43c7-bbd9-fe30c69c76f8'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Aug 2020 17:01:53

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-23T12:01:48', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '61052662-ffaa-43c7-bbd9-fe30c69c76f8'	(b) (4), (b) (6) System	23 Aug 2020 17:01:53
User entered '23 Aug 2020 12:01'	System	23 Aug 2020 17:01:53

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 5'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:09:05', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5fceb10-0fac-4093-a98e-ee467209171f'	(b) (4), (b) (6)	
User entered 'None (0)'	System	24 Aug 2020 19:09:33

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:09:09', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5fceb10-0fac-4093-a98e-ee467209171f'	(b) (4), (b) (6)	
User entered 'None (0)'	System	24 Aug 2020 19:09:33

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:09:12', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5fceb10-0fac-4093-a98e-ee467209171f'	(b) (4), (b) (6)	
User entered 'None (0)'	System	24 Aug 2020 19:09:33

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:09:16', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5fceb10-0fac-4093-a98e-ee467209171f'	(b) (4), (b) (6)	
User entered 'None (0)'	System	24 Aug 2020 19:09:33

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:09:18', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5fceb10-0fac-4093-a98e-ee467209171f'	(b) (4), (b) (6)	
User entered 'None (0)'	System	24 Aug 2020 19:09:33

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:09:23', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5fceb10-0fac-4093-a98e-ee467209171f'	(b) (4), (b) (6)	
User entered 'None (0)'	System	24 Aug 2020 19:09:33

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:09:27', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5fceb10-0fac-4093-a98e-ee467209171f'	(b) (4), (b) (6)	
User entered 'No (N)'	System	24 Aug 2020 19:09:33

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-24T14:09:30', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5fceb10-0fac-4093-a98e-ee467209171f'	(b) (4), (b) (6) System	24 Aug 2020 19:09:33
User entered '24 Aug 2020 14:09'	System	24 Aug 2020 19:09:33

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 6'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:26', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'be906284-15f6-4272-928e-6d86687ec4f2'	(b) (4), (b) (6)	
	System	25 Aug 2020 17:02:52
User entered 'None (0)'	System	25 Aug 2020 17:02:52

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:30', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'be906284-15f6-4272-928e-6d86687ec4f2'	(b) (4), (b) (6)	
	System	25 Aug 2020 17:02:52
User entered 'None (0)'	System	25 Aug 2020 17:02:52

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:32', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'be906284-15f6-4272-928e-6d86687ec4f2'	(b) (4), (b) (6)	
User entered 'None (0)'	System	25 Aug 2020 17:02:52

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:36', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'be906284-15f6-4272-928e-6d86687ec4f2'	(b) (4), (b) (6)	
User entered 'None (0)'	System	25 Aug 2020 17:02:52

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:39', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'be906284-15f6-4272-928e-6d86687ec4f2'	(b) (4), (b) (6)	
	System	25 Aug 2020 17:02:52
User entered 'None (0)'	System	25 Aug 2020 17:02:52

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:41', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'be906284-15f6-4272-928e-6d86687ec4f2'	(b) (4), (b) (6)	
	System	25 Aug 2020 17:02:52
User entered 'None (0)'	System	25 Aug 2020 17:02:52

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:45', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'be906284-15f6-4272-928e-6d86687ec4f2'	(b) (4), (b) (6)	
	System	25 Aug 2020 17:02:52
User entered 'No (N)'	System	25 Aug 2020 17:02:52

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-25T12:02:47', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'be906284-15f6-4272-928e-6d86687ec4f2'	(b) (4), (b) (6)	
	System	25 Aug 2020 17:02:52
User entered '25 Aug 2020 12:02'	System	25 Aug 2020 17:02:52

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 7'	System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:38', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '34a64e4f-023d-4b9c-bb8a-009f5006c5d7'	(b) (4), (b) (6)	
User entered 'None (0)'	System	26 Aug 2020 17:02:10

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:40', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '34a64e4f-023d-4b9c-bb8a-009f5006c5d7'	(b) (4), (b) (6)	
User entered 'None (0)'	System	26 Aug 2020 17:02:10

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:42', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '34a64e4f-023d-4b9c-bb8a-009f5006c5d7'	(b) (4), (b) (6)	
User entered 'None (0)'	System	26 Aug 2020 17:02:10

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:44', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '34a64e4f-023d-4b9c-bb8a-009f5006c5d7'	(b) (4), (b) (6)	
User entered 'None (0)'	System	26 Aug 2020 17:02:10

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:46', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '34a64e4f-023d-4b9c-bb8a-009f5006c5d7'	(b) (4), (b) (6)	
User entered 'None (0)'	System	26 Aug 2020 17:02:10

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:48', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '34a64e4f-023d-4b9c-bb8a-009f5006c5d7'	(b) (4), (b) (6)	
	System	26 Aug 2020 17:02:10
User entered 'None (0)'	System	26 Aug 2020 17:02:10

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

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 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:50', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '34a64e4f-023d-4b9c-bb8a-009f5006c5d7'	(b) (4), (b) (6)	
User entered 'No (N)'	System	26 Aug 2020 17:02:10

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-08-26T12:01:53', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '34a64e4f-023d-4b9c-bb8a-009f5006c5d7'	(b) (4), (b) (6)	
	System	26 Aug 2020 17:02:10
User entered '26 Aug 2020 12:01'	System	26 Aug 2020 17:02:10

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:50
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 21:10:15

US3042264

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:19:06
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:48:45

US3042264

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:19:06
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 07:09:16
User entered '27 Aug 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:49:43
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'SUBJECT WAS LEFT A MESSAGE AND REACHED BACK OUT TO US TODAY' (Site from System).	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:49:25
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Sep 2020 17:48:45
User entered '03 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:48:45

US3042264

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:19:06
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:48:45

US3042264

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:19:06
User entered empty.	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:48:45

US3042264

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:19:21
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:49:29

US3042264

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:58:06
User entered 'I'	System	03 Sep 2020 17:49:29

US3042264

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:50:17
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:19:35
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:49:54

US3042264

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:50:17
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:19:35
User entered '03 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:49:54

US3042264

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:50:17
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:19:35
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:49:54

US3042264

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:50:17
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:19:35
User entered empty.	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:49:54

US3042264

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:50:17
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:19:45
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	03 Sep 2020 17:49:56

US3042264

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:50:17
User entered 'I'	System	03 Sep 2020 17:49:56

US3042264

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:38:28
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:11
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 19:19:04

US3042264

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:38:28
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:11
User entered '10 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 19:19:04

US3042264

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:38:28
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:11
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 19:19:04

US3042264

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:38:28
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:11
User entered empty.	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 19:19:04

US3042264

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:38:28
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:20
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	10 Sep 2020 19:19:06

US3042264

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:38:28
User entered 'I'	System	10 Sep 2020 19:19:06

US3042264

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:34
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	17 Sep 2020 12:46:47
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:34
User entered '17 Sep 2020'	Jamie Thompson (b) (4)	17 Sep 2020 12:46:47
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:34
User entered 'Clinic (Clinic)'	Jamie Thompson (b) (4)	17 Sep 2020 12:46:47
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered 'VISIT2'	(b) (4), (b) (6) System	17 Sep 2020 12:46:47

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Jamie Thompson (b) (4)	17 Sep 2020 12:47:27
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	17 Sep 2020 12:47:27
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '17 Sep 2020'	Jamie Thompson (b) (4)	17 Sep 2020 12:47:27
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '06:59'	Jamie Thompson (b) (4)	17 Sep 2020 12:47:27
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered '17 Sep 2020 06:59'	(b) (4), (b) (6) System	17 Sep 2020 12:47:27

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '37.1' C	Jamie Thompson (b) (4)	17 Sep 2020 12:47:27
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered 'Oral (Oral)'	Jamie Thompson (b) (4)	17 Sep 2020 12:47:27
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered empty.	Jamie Thompson (b) (4)	17 Sep 2020 12:47:27
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '55'	Jamie Thompson (b) (4)	17 Sep 2020 12:47:27
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered 'bpm'	(b) (4), (b) (6) System	17 Sep 2020 12:47:27

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '12'	Jamie Thompson (b) (4)	17 Sep 2020 12:47:27
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Sep 2020 12:47:27

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '134'	Jamie Thompson (b) (4)	17 Sep 2020 12:47:27
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered 'mmHg'	(b) (4), (b) (6) System	17 Sep 2020 12:47:27

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '76'	Jamie Thompson (b) (4)	17 Sep 2020 12:47:27
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered 'mmHg'	(b) (4), (b) (6) System	17 Sep 2020 12:47:27

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	17 Sep 2020 14:05:00

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Sep 2020 14:05:00
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '17 Sep 2020'	Rylea Gulick (b) (4)	17 Sep 2020 14:05:00
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '08:17'	Rylea Gulick (b) (4)	17 Sep 2020 14:05:00
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered '17 Sep 2020 08:17'	(b) (4), (b) (6) System	17 Sep 2020 14:05:00

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '37.0' C	Rylea Gulick (b) (4)	17 Sep 2020 14:05:00
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	17 Sep 2020 14:05:00
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered empty.	Rylea Gulick (b) (4)	17 Sep 2020 14:05:00
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '62'	Rylea Gulick (b) (4)	17 Sep 2020 14:05:00
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered 'bpm'	(b) (4), (b) (6) System	17 Sep 2020 14:05:00

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '12'	Rylea Gulick (b) (4)	17 Sep 2020 14:05:00
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Sep 2020 14:05:00

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '130'	Rylea Gulick (b) (4)	17 Sep 2020 14:05:00
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered 'mmHg'	(b) (4), (b) (6) System	17 Sep 2020 14:05:00

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:42
User entered '78'	Rylea Gulick (b) (4)	17 Sep 2020 14:05:00
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered 'mmHg'	(b) (4), (b) (6) System	17 Sep 2020 14:05:00

US3042264

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:51
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	17 Sep 2020 12:47:44
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:20:51
User entered '17 Sep 2020'	Jamie Thompson (b) (4)	17 Sep 2020 12:47:44
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:00
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:09
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:00
User entered empty.	Jamie Thompson (b) (4)	17 Sep 2020 12:48:09
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:00
User entered empty.	Jamie Thompson (b) (4)	17 Sep 2020 12:48:09
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:00
User entered '17 Sep 2020'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:09
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:00
User entered '07:43'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:09
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered '17 Sep 2020 07:43'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:00
User entered 'Left Arm (LEFT ARM)'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:09
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:00
User entered 'ONCE'	System	17 Sep 2020 12:48:09

US3042264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:12
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:30
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:12
User entered '17 Sep 2020'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:30
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:12
User entered '07:10'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:30
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered '17 Sep 2020 07:10'	(b) (4), (b) (6) System	17 Sep 2020 12:48:30

US3042264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:56:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:21
User entered '17 Sep 2020'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:43
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:43
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:21
User entered 'Yes (Y)'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:43
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:21
User entered '07:20'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:43
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered '17 Sep 2020 07:20'	(b) (4), (b) (6) System	17 Sep 2020 12:48:43

US3042264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:43
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:21
User entered 'No (N)'	Jamie Thompson (b) (4)	17 Sep 2020 12:48:43
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:21
User entered empty.	Jamie Thompson (b) (4)	17 Sep 2020 12:48:43
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered empty.	(b) (4), (b) (6) System	17 Sep 2020 12:48:43

US3042264

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:21:31
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Sep 2020 14:05:10
	(b) (4)	

US3042264

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:09
User entered '1'	(b) (4), (b) (6) System	17 Sep 2020 14:05:10

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:11:21', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '902b4a33-b9f7-45cc-a92d-d8ca2f5a8703'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	17 Sep 2020 13:11:41

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:11:28', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '902b4a33-b9f7-45cc-a92d-d8ca2f5a8703'	(b) (4), (b) (6) System	17 Sep 2020 13:11:41
User entered '98.6'	System	17 Sep 2020 13:11:41

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:11:33', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '902b4a33-b9f7-45cc-a92d-d8ca2f5a8703'	(b) (4), (b) (6) System	17 Sep 2020 13:11:41
User entered 'No (N)'	System	17 Sep 2020 13:11:41

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:11:39', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '902b4a33-b9f7-45cc-a92d-d8ca2f5a8703'	(b) (4), (b) (6) System	17 Sep 2020 13:11:41
User entered '17 Sep 2020 08:11'	System	17 Sep 2020 13:11:41

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '17 Sep 2020 08:03'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '17 Sep 2020 10:33'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:35:54', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '19260678-a41b-472e-a231-663dc071f2c8'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	17 Sep 2020 16:36:13

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:03', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '19260678-a41b-472e-a231-663dc071f2c8'	(b) (4), (b) (6)	
User entered '98.6'	System	17 Sep 2020 16:36:13

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:07', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '19260678-a41b-472e-a231-663dc071f2c8'	(b) (4), (b) (6)	
	System	17 Sep 2020 16:36:13
User entered 'No (N)'	System	17 Sep 2020 16:36:13

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:10', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '19260678-a41b-472e-a231-663dc071f2c8'	(b) (4), (b) (6) System	17 Sep 2020 16:36:13
User entered '17 Sep 2020 11:36'	System	17 Sep 2020 16:36:13

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '17 Sep 2020 11:28'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 2'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:00:34', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5a7666f6-e91a-4c80-85b5-681cfdbf8dfa'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	18 Sep 2020 17:01:20

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:00:41', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5a7666f6-e91a-4c80-85b5-681cfdbf8dfa' User entered '98.2'	(b) (4), (b) (6) System	18 Sep 2020 17:01:20
	System	18 Sep 2020 17:01:20

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:00:45', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5a7666f6-e91a-4c80-85b5-681cfdbf8dfa'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Sep 2020 17:01:20

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:00:49', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '5a7666f6-e91a-4c80-85b5-681cfdbf8dfa'	(b) (4), (b) (6) System	18 Sep 2020 17:01:20
User entered '18 Sep 2020 12:00'	System	18 Sep 2020 17:01:20

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 3'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:03', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '1cedae3f-4234-48c8-9610-8ec812b1c4af'	(b) (4), (b) (6) System	19 Sep 2020 17:01:42
User entered 'Yes (Y)'	System	19 Sep 2020 17:01:42

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:11', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '1cedae3f-4234-48c8-9610-8ec812b1c4af'	(b) (4), (b) (6) System	19 Sep 2020 17:01:42
User entered '97.6'	System	19 Sep 2020 17:01:42

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:15', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '1cedae3f-4234-48c8-9610-8ec812b1c4af'	(b) (4), (b) (6) System	19 Sep 2020 17:01:42
User entered 'No (N)'	System	19 Sep 2020 17:01:42

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:18', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '1cedae3f-4234-48c8-9610-8ec812b1c4af'	(b) (4), (b) (6) System	19 Sep 2020 17:01:42
User entered '19 Sep 2020 12:01'	System	19 Sep 2020 17:01:42

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 4'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:15:58', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '06bfcd95-a574-4259-a0e9-aac84ecc5472'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	20 Sep 2020 17:16:17

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:06', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '06bfcd95-a574-4259-a0e9-aac84ecc5472'	(b) (4), (b) (6)	
User entered '98.2'	System	20 Sep 2020 17:16:17

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:10', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '06bfcd95-a574-4259-a0e9-aac84ecc5472'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Sep 2020 17:16:17

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:15', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '06bfcd95-a574-4259-a0e9-aac84ecc5472'	(b) (4), (b) (6) System	20 Sep 2020 17:16:17
User entered '20 Sep 2020 12:16'	System	20 Sep 2020 17:16:17

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 5'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:00:41', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2ea2ad54-2a72-48a3-97cc-dd4804fb11b2'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	21 Sep 2020 17:03:46

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:00:46', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2ea2ad54-2a72-48a3-97cc-dd4804fb11b2'	(b) (4), (b) (6)	
User entered '98.2'	System	21 Sep 2020 17:03:46

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:00:52', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2ea2ad54-2a72-48a3-97cc-dd4804fb11b2'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Sep 2020 17:03:46

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:00:55', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2ea2ad54-2a72-48a3-97cc-dd4804fb11b2'	(b) (4), (b) (6) System	21 Sep 2020 17:03:46
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 17:03:46

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '21 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '22 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 6'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:21:58', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '571db086-c186-4508-8872-028065f6c7bd'	(b) (4), (b) (6)	
	System	23 Sep 2020 16:22:17
User entered 'Yes (Y)'	System	23 Sep 2020 16:22:17

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:06', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '571db086-c186-4508-8872-028065f6c7bd' User entered '98.6'	(b) (4), (b) (6) System	23 Sep 2020 16:22:17
	System	23 Sep 2020 16:22:17

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:09', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '571db086-c186-4508-8872-028065f6c7bd'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Sep 2020 16:22:17

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:13', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '571db086-c186-4508-8872-028065f6c7bd' User entered '23 Sep 2020 11:22'	(b) (4), (b) (6) System	23 Sep 2020 16:22:17
	System	23 Sep 2020 16:22:17

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '22 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '23 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 7'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:19', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'bc47e3f1-9158-4271-b5f9-80f02de01f66'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	23 Sep 2020 17:05:10

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:27', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'bc47e3f1-9158-4271-b5f9-80f02de01f66'	(b) (4), (b) (6)	23 Sep 2020 17:05:10
User entered '98.2'	System	23 Sep 2020 17:05:10

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:30', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'bc47e3f1-9158-4271-b5f9-80f02de01f66'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Sep 2020 17:05:10

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:34', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'bc47e3f1-9158-4271-b5f9-80f02de01f66'	(b) (4), (b) (6)	
	System	23 Sep 2020 17:05:10
User entered '23 Sep 2020 12:01'	System	23 Sep 2020 17:05:10

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '23 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '24 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:12:39', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '01aea1af-2d56-4b80-bb4e-705df70650b1'	(b) (4), (b) (6)	
	System	17 Sep 2020 13:13:00
User entered 'None (1)'	System	17 Sep 2020 13:13:00

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:12:43', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '01aea1af-2d56-4b80-bb4e-705df70650b1'	(b) (4), (b) (6)	
User entered 'No (N)'	System	17 Sep 2020 13:13:00

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:12:47', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '01aea1af-2d56-4b80-bb4e-705df70650b1'	(b) (4), (b) (6)	
User entered 'No (N)'	System	17 Sep 2020 13:13:00

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:12:51', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '01aea1af-2d56-4b80-bb4e-705df70650b1'	(b) (4), (b) (6) System	17 Sep 2020 13:13:00
User entered 'None (1)'	System	17 Sep 2020 13:13:00

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:12:55', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '01aea1af-2d56-4b80-bb4e-705df70650b1'	(b) (4), (b) (6) System	17 Sep 2020 13:13:00
User entered '17 Sep 2020 08:12'	System	17 Sep 2020 13:13:00

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '17 Sep 2020 08:03'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '17 Sep 2020 10:33'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:18', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '450ff9e3-79a9-4537-9f00-44554c7fee11'	(b) (4), (b) (6) System	17 Sep 2020 16:36:38
User entered 'None (1)'	System	17 Sep 2020 16:36:38

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:21', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '450ff9e3-79a9-4537-9f00-44554c7fee11'	(b) (4), (b) (6)	
User entered 'No (N)'	System	17 Sep 2020 16:36:38

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:23', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '450ff9e3-79a9-4537-9f00-44554c7fee11'	(b) (4), (b) (6) System	17 Sep 2020 16:36:38
User entered 'No (N)'	System	17 Sep 2020 16:36:38

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:26', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '450ff9e3-79a9-4537-9f00-44554c7fee11'	(b) (4), (b) (6) System	17 Sep 2020 16:36:38
User entered 'None (1)'	System	17 Sep 2020 16:36:38

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:32', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '450ff9e3-79a9-4537-9f00-44554c7fee11'	(b) (4), (b) (6) System	17 Sep 2020 16:36:38
User entered '17 Sep 2020 11:36'	System	17 Sep 2020 16:36:38

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '17 Sep 2020 11:28'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 2'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:00:54', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '602ad0fd-9676-4f13-9ab6-7393a12633db'	(b) (4), (b) (6)	
	System	18 Sep 2020 17:01:44
User entered 'None (1)'	System	18 Sep 2020 17:01:44

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:00:57', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '602ad0fd-9676-4f13-9ab6-7393a12633db'	(b) (4), (b) (6)	
	System	18 Sep 2020 17:01:44
User entered 'No (N)'	System	18 Sep 2020 17:01:44

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:01:00', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '602ad0fd-9676-4f13-9ab6-7393a12633db'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Sep 2020 17:01:44

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:01:02', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '602ad0fd-9676-4f13-9ab6-7393a12633db'	(b) (4), (b) (6)	
	System	18 Sep 2020 17:01:44
User entered 'None (1)'	System	18 Sep 2020 17:01:44

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:01:05', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '602ad0fd-9676-4f13-9ab6-7393a12633db'	(b) (4), (b) (6) System	18 Sep 2020 17:01:44
User entered '18 Sep 2020 12:01'	System	18 Sep 2020 17:01:44

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 3'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:23', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e011209e-aded-409f-a6c7-cbb51ce4fe90'	(b) (4), (b) (6) System	19 Sep 2020 17:01:57
User entered 'None (1)'	System	19 Sep 2020 17:01:57

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:26', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e011209e-aded-409f-a6c7-cbb51ce4fe90'	(b) (4), (b) (6)	
User entered 'No (N)'	System	19 Sep 2020 17:01:57

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:29', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e011209e-aded-409f-a6c7-cbb51ce4fe90'	(b) (4), (b) (6)	
User entered 'No (N)'	System	19 Sep 2020 17:01:57

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:32', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e011209e-aded-409f-a6c7-cbb51ce4fe90'	(b) (4), (b) (6) System	19 Sep 2020 17:01:57
User entered 'None (1)'	System	19 Sep 2020 17:01:57

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:34', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e011209e-aded-409f-a6c7-cbb51ce4fe90'	(b) (4), (b) (6)	
User entered '19 Sep 2020 12:01'	System	19 Sep 2020 17:01:57

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 4'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:20', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2fb2e87a-ac64-431e-b79e-e99adfeb2e8f'	(b) (4), (b) (6) System	20 Sep 2020 17:16:36
User entered 'None (1)'	System	20 Sep 2020 17:16:36

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:24', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2fb2e87a-ac64-431e-b79e-e99adfeb2e8f'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Sep 2020 17:16:36

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:27', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2fb2e87a-ac64-431e-b79e-e99adfeb2e8f'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Sep 2020 17:16:36

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:30', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2fb2e87a-ac64-431e-b79e-e99adfeb2e8f'	(b) (4), (b) (6)	20 Sep 2020 17:16:36
User entered 'None (1)'	System	20 Sep 2020 17:16:36

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:33', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2fb2e87a-ac64-431e-b79e-e99adfeb2e8f' User entered '20 Sep 2020 12:16'	(b) (4), (b) (6) System	20 Sep 2020 17:16:36
	System	20 Sep 2020 17:16:36

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 5'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:03', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '4139e91b-0c58-4484-8283-2ff860dae280'	(b) (4), (b) (6)	21 Sep 2020 17:04:19
User entered 'None (1)'	System	21 Sep 2020 17:04:19

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:05', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '4139e91b-0c58-4484-8283-2ff860dae280'	(b) (4), (b) (6)	
	System	21 Sep 2020 17:04:19
User entered 'No (N)'	System	21 Sep 2020 17:04:19

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:08', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '4139e91b-0c58-4484-8283-2ff860dae280'	(b) (4), (b) (6)	
	System	21 Sep 2020 17:04:19
User entered 'No (N)'	System	21 Sep 2020 17:04:19

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:11', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '4139e91b-0c58-4484-8283-2ff860dae280'	(b) (4), (b) (6)	21 Sep 2020 17:04:19
User entered 'None (1)'	System	21 Sep 2020 17:04:19

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:14', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '4139e91b-0c58-4484-8283-2ff860dae280'	(b) (4), (b) (6) System	21 Sep 2020 17:04:19
User entered '21 Sep 2020 12:01'	System	21 Sep 2020 17:04:19

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '21 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '22 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 6'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:18', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '23001473-7081-4030-9c4b-f4b09eeb18a6'	(b) (4), (b) (6)	23 Sep 2020 16:22:35
User entered 'None (1)'	System	23 Sep 2020 16:22:35

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:21', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '23001473-7081-4030-9c4b-f4b09eeb18a6'	(b) (4), (b) (6)	23 Sep 2020 16:22:35
User entered 'No (N)'	System	23 Sep 2020 16:22:35

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:23', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '23001473-7081-4030-9c4b-f4b09eeb18a6'	(b) (4), (b) (6)	23 Sep 2020 16:22:35
User entered 'No (N)'	System	23 Sep 2020 16:22:35

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:26', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '23001473-7081-4030-9c4b-f4b09eeb18a6'	(b) (4), (b) (6)	23 Sep 2020 16:22:35
User entered 'None (1)'	System	23 Sep 2020 16:22:35

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:29', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '23001473-7081-4030-9c4b-f4b09eeb18a6'	(b) (4), (b) (6) System	23 Sep 2020 16:22:35
User entered '23 Sep 2020 11:22'	System	23 Sep 2020 16:22:35

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '22 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '23 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 7'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:37', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'cc3d13a1-70db-4077-b805-8f8fc820f7df'	(b) (4), (b) (6) System	23 Sep 2020 17:05:31
User entered 'None (1)'	System	23 Sep 2020 17:05:31

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:40', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'cc3d13a1-70db-4077-b805-8f8fc820f7df'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Sep 2020 17:05:31

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:43', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'cc3d13a1-70db-4077-b805-8f8fc820f7df'	(b) (4), (b) (6)	
	System	23 Sep 2020 17:05:31
User entered 'No (N)'	System	23 Sep 2020 17:05:31

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:45', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'cc3d13a1-70db-4077-b805-8f8fc820f7df'	(b) (4), (b) (6)	23 Sep 2020 17:05:31
User entered 'None (1)'	System	23 Sep 2020 17:05:31

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:48', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'cc3d13a1-70db-4077-b805-8f8fc820f7df'	(b) (4), (b) (6) System	23 Sep 2020 17:05:31
User entered '23 Sep 2020 12:01'	System	23 Sep 2020 17:05:31

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '23 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '24 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:14:16', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9c7d4ac2-5a28-413e-9a6a-1ceb5cde0944'	(b) (4), (b) (6)	
User entered 'None (0)'	System	17 Sep 2020 13:14:47

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:14:20', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9c7d4ac2-5a28-413e-9a6a-1ceb5cde0944'	(b) (4), (b) (6)	
	System	17 Sep 2020 13:14:47
User entered 'None (0)'	System	17 Sep 2020 13:14:47

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:14:24', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9c7d4ac2-5a28-413e-9a6a-1ceb5cde0944'	(b) (4), (b) (6) System	17 Sep 2020 13:14:47
User entered 'None (0)'	System	17 Sep 2020 13:14:47

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:14:28', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9c7d4ac2-5a28-413e-9a6a-1ceb5cde0944'	(b) (4), (b) (6)	
User entered 'None (0)'	System	17 Sep 2020 13:14:47

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:14:31', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9c7d4ac2-5a28-413e-9a6a-1ceb5cde0944'	(b) (4), (b) (6)	
User entered 'None (0)'	System	17 Sep 2020 13:14:47

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:14:34', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9c7d4ac2-5a28-413e-9a6a-1ceb5cde0944'	(b) (4), (b) (6) System	17 Sep 2020 13:14:47
User entered 'None (0)'	System	17 Sep 2020 13:14:47

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:14:39', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9c7d4ac2-5a28-413e-9a6a-1ceb5cde0944'	(b) (4), (b) (6)	
User entered 'No (N)'	System	17 Sep 2020 13:14:47

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T08:14:43', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '9c7d4ac2-5a28-413e-9a6a-1ceb5cde0944'	(b) (4), (b) (6)	
	System	17 Sep 2020 13:14:47
User entered '17 Sep 2020 08:14'	System	17 Sep 2020 13:14:47

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '17 Sep 2020 08:03'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '17 Sep 2020 10:33'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:39', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0a0744f9-421a-4f13-8196-ceb5d433ed89'	(b) (4), (b) (6)	
	System	17 Sep 2020 16:36:58
User entered 'None (0)'	System	17 Sep 2020 16:36:58

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:42', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0a0744f9-421a-4f13-8196-ceb5d433ed89'	(b) (4), (b) (6)	
User entered 'None (0)'	System	17 Sep 2020 16:36:58

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:44', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0a0744f9-421a-4f13-8196-ceb5d433ed89'	(b) (4), (b) (6)	
User entered 'None (0)'	System	17 Sep 2020 16:36:58

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:46', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0a0744f9-421a-4f13-8196-ceb5d433ed89'	(b) (4), (b) (6)	
User entered 'None (0)'	System	17 Sep 2020 16:36:58

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:48', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0a0744f9-421a-4f13-8196-ceb5d433ed89'	(b) (4), (b) (6)	
	System	17 Sep 2020 16:36:58
User entered 'None (0)'	System	17 Sep 2020 16:36:58

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:50', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0a0744f9-421a-4f13-8196-ceb5d433ed89'	(b) (4), (b) (6)	
	System	17 Sep 2020 16:36:58
User entered 'None (0)'	System	17 Sep 2020 16:36:58

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:52', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0a0744f9-421a-4f13-8196-ceb5d433ed89'	(b) (4), (b) (6) System	17 Sep 2020 16:36:58
User entered 'No (N)'	System	17 Sep 2020 16:36:58

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-17T11:36:55', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '0a0744f9-421a-4f13-8196-ceb5d433ed89'	(b) (4), (b) (6) System	17 Sep 2020 16:36:58
User entered '17 Sep 2020 11:36'	System	17 Sep 2020 16:36:58

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '17 Sep 2020 11:28'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '18 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 2'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:01:11', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '55161f26-7a89-418d-9679-50029564ddff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	18 Sep 2020 17:02:14

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:01:13', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '55161f26-7a89-418d-9679-50029564ddff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	18 Sep 2020 17:02:14

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:01:15', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '55161f26-7a89-418d-9679-50029564ddff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	18 Sep 2020 17:02:14

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:01:17', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '55161f26-7a89-418d-9679-50029564ddff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	18 Sep 2020 17:02:14

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:01:19', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '55161f26-7a89-418d-9679-50029564ddff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	18 Sep 2020 17:02:14

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:01:21', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '55161f26-7a89-418d-9679-50029564ddff'	(b) (4), (b) (6)	
User entered 'None (0)'	System	18 Sep 2020 17:02:14

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:01:24', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '55161f26-7a89-418d-9679-50029564ddff'	(b) (4), (b) (6)	
User entered 'No (N)'	System	18 Sep 2020 17:02:14

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-18T12:01:27', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '55161f26-7a89-418d-9679-50029564ddff'	(b) (4), (b) (6) System	18 Sep 2020 17:02:14
User entered '18 Sep 2020 12:01'	System	18 Sep 2020 17:02:14

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '18 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '19 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 3'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:39', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e264ebef-71c1-45bf-b367-c12eb284e6f7'	(b) (4), (b) (6)	
User entered 'None (0)'	System	19 Sep 2020 17:02:27

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:41', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e264ebef-71c1-45bf-b367-c12eb284e6f7'	(b) (4), (b) (6)	
User entered 'None (0)'	System	19 Sep 2020 17:02:27

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:44', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e264ebef-71c1-45bf-b367-c12eb284e6f7'	(b) (4), (b) (6)	
User entered 'None (0)'	System	19 Sep 2020 17:02:27

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:46', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e264ebef-71c1-45bf-b367-c12eb284e6f7'	(b) (4), (b) (6)	
User entered 'None (0)'	System	19 Sep 2020 17:02:27

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:48', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e264ebef-71c1-45bf-b367-c12eb284e6f7'	(b) (4), (b) (6)	
User entered 'None (0)'	System	19 Sep 2020 17:02:27

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:51', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e264ebef-71c1-45bf-b367-c12eb284e6f7'	(b) (4), (b) (6)	
User entered 'None (0)'	System	19 Sep 2020 17:02:27

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:55', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e264ebef-71c1-45bf-b367-c12eb284e6f7'	(b) (4), (b) (6)	
User entered 'No (N)'	System	19 Sep 2020 17:02:27

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-19T12:01:58', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e264ebef-71c1-45bf-b367-c12eb284e6f7'	(b) (4), (b) (6) System	19 Sep 2020 17:02:27
User entered '19 Sep 2020 12:01'	System	19 Sep 2020 17:02:27

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '19 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '20 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 4'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:37', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a4886e-27da-4af6-8174-a6dc94a385c0'	(b) (4), (b) (6)	
	System	20 Sep 2020 17:17:13
User entered 'None (0)'	System	20 Sep 2020 17:17:13

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:42', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a4886e-27da-4af6-8174-a6dc94a385c0'	(b) (4), (b) (6)	
	System	20 Sep 2020 17:17:13
User entered 'None (0)'	System	20 Sep 2020 17:17:13

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:45', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a4886e-27da-4af6-8174-a6dc94a385c0'	(b) (4), (b) (6)	
	System	20 Sep 2020 17:17:13
User entered 'None (0)'	System	20 Sep 2020 17:17:13

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:48', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a4886e-27da-4af6-8174-a6dc94a385c0'	(b) (4), (b) (6)	
	System	20 Sep 2020 17:17:13
User entered 'None (0)'	System	20 Sep 2020 17:17:13

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:50', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a4886e-27da-4af6-8174-a6dc94a385c0'	(b) (4), (b) (6)	
	System	20 Sep 2020 17:17:13
User entered 'None (0)'	System	20 Sep 2020 17:17:13

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:53', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a4886e-27da-4af6-8174-a6dc94a385c0'	(b) (4), (b) (6)	
User entered 'None (0)'	System	20 Sep 2020 17:17:13

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:55', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a4886e-27da-4af6-8174-a6dc94a385c0'	(b) (4), (b) (6)	
	System	20 Sep 2020 17:17:13
User entered 'No (N)'	System	20 Sep 2020 17:17:13

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-20T12:16:58', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b6a4886e-27da-4af6-8174-a6dc94a385c0'	(b) (4), (b) (6) System	20 Sep 2020 17:17:13
User entered '20 Sep 2020 12:16'	System	20 Sep 2020 17:17:13

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '20 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '21 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 5'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:19', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '73948d52-67bc-477f-8894-4f3114d06af5'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Sep 2020 17:04:48

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:21', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '73948d52-67bc-477f-8894-4f3114d06af5'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Sep 2020 17:04:48

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:23', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '73948d52-67bc-477f-8894-4f3114d06af5'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Sep 2020 17:04:48

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:26', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '73948d52-67bc-477f-8894-4f3114d06af5'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Sep 2020 17:04:48

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:27', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '73948d52-67bc-477f-8894-4f3114d06af5'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Sep 2020 17:04:48

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:29', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '73948d52-67bc-477f-8894-4f3114d06af5'	(b) (4), (b) (6)	
	System	21 Sep 2020 17:04:48
User entered 'None (0)'	System	21 Sep 2020 17:04:48

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:31', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '73948d52-67bc-477f-8894-4f3114d06af5'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Sep 2020 17:04:48

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-21T12:01:34', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '73948d52-67bc-477f-8894-4f3114d06af5'	(b) (4), (b) (6)	
	System	21 Sep 2020 17:04:48
User entered '21 Sep 2020 12:01'	System	21 Sep 2020 17:04:48

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '21 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '22 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 6'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:33', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '42db0d49-d853-4571-9c32-34bae58135fe'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 16:22:52

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:35', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '42db0d49-d853-4571-9c32-34bae58135fe'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 16:22:52

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:38', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '42db0d49-d853-4571-9c32-34bae58135fe'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 16:22:52

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:39', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '42db0d49-d853-4571-9c32-34bae58135fe' User entered 'None (0)'	(b) (4), (b) (6) System	23 Sep 2020 16:22:52
	System	23 Sep 2020 16:22:52

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:41', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '42db0d49-d853-4571-9c32-34bae58135fe'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 16:22:52

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:44', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '42db0d49-d853-4571-9c32-34bae58135fe'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 16:22:52

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:47', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '42db0d49-d853-4571-9c32-34bae58135fe'	(b) (4), (b) (6)	
	System	23 Sep 2020 16:22:52
User entered 'No (N)'	System	23 Sep 2020 16:22:52

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T11:22:49', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '42db0d49-d853-4571-9c32-34bae58135fe'	(b) (4), (b) (6)	
	System	23 Sep 2020 16:22:52
User entered '23 Sep 2020 11:22'	System	23 Sep 2020 16:22:52

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '22 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '23 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	17 Sep 2020 12:48:09
User entered 'Day 7'	System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:52', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e8a695c3-dc89-4891-8baa-16bdf425fe07'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 17:06:12

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:54', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e8a695c3-dc89-4891-8baa-16bdf425fe07'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 17:06:12

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:56', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e8a695c3-dc89-4891-8baa-16bdf425fe07'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 17:06:12

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:57', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e8a695c3-dc89-4891-8baa-16bdf425fe07'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 17:06:12

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:01:59', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e8a695c3-dc89-4891-8baa-16bdf425fe07'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 17:06:12

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:02:01', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e8a695c3-dc89-4891-8baa-16bdf425fe07'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Sep 2020 17:06:12

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

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 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:02:05', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e8a695c3-dc89-4891-8baa-16bdf425fe07'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Sep 2020 17:06:12

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-09-23T12:02:16', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e8a695c3-dc89-4891-8baa-16bdf425fe07'	(b) (4), (b) (6)	
	System	23 Sep 2020 17:06:12
User entered '23 Sep 2020 12:02'	System	23 Sep 2020 17:06:12

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '23 Sep 2020 12:00'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
User entered '24 Sep 2020 11:59'	(b) (4), (b) (6) System	17 Sep 2020 12:48:09

US3042264

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:14
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:21:48
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 18:16:55

US3042264

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:14
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:21:48
User entered '24 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 18:16:55

US3042264

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:14
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:21:48
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 18:16:55

US3042264

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:14
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:21:48
User entered empty.	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 18:16:55

US3042264

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:14
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:21:58
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	24 Sep 2020 18:16:58

US3042264

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:14
User entered 'I'	System	24 Sep 2020 18:16:58

US3042264

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:31
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:22:09
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 20:30:27

US3042264

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:31
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:22:09
User entered '01 Oct 2020'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 20:30:27

US3042264

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:31
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:22:09
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 20:30:27

US3042264

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:31
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:22:09
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 20:30:27

US3042264

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:31
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:22:19
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	01 Oct 2020 20:30:29

US3042264

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:10:31
User entered 'I'	System	01 Oct 2020 20:30:29

US3042264

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:59:17
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:31
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	08 Oct 2020 20:40:54
	(b) (4)	

US3042264

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:59:17
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:31
User entered '08 Oct 2020'	Rylea Gulick (b) (4)	08 Oct 2020 20:40:54
	(b) (4)	

US3042264

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:59:17
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:31
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	08 Oct 2020 20:40:54
	(b) (4)	

US3042264

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:59:17
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:31
User entered empty.	Rylea Gulick (b) (4)	08 Oct 2020 20:40:54
	(b) (4)	

US3042264

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:59:17
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:40
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	08 Oct 2020 20:40:55
	(b) (4)	

US3042264

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:59:17
User entered '1'	System	08 Oct 2020 20:40:55

US3042264

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:54
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Oct 2020 15:39:52
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:54
User entered '15 Oct 2020'	Rylea Gulick (b) (4)	15 Oct 2020 15:39:52
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:22:54
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	15 Oct 2020 15:39:52
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
User entered 'VISIT3'	(b) (4), (b) (6) System	15 Oct 2020 15:39:52

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:02
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:04
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:02
User entered '15 Oct 2020'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:04
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:02
User entered '08:05'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:04
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
User entered '15 Oct 2020 08:05'	(b) (4), (b) (6) System	15 Oct 2020 15:40:04

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:02
User entered '37.1' C	Rylea Gulick (b) (4)	15 Oct 2020 15:40:04
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:02
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:04
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:02
User entered empty.	Rylea Gulick (b) (4)	15 Oct 2020 15:40:04
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:02
User entered '64'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:04
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
User entered 'bpm'	(b) (4), (b) (6) System	15 Oct 2020 15:40:04

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:02
User entered '14'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:04
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Oct 2020 15:40:04

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:02
User entered '128'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:04
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
User entered 'mmHg'	(b) (4), (b) (6) System	15 Oct 2020 15:40:04

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:02
User entered '71'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:04
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
User entered 'mmHg'	(b) (4), (b) (6) System	15 Oct 2020 15:40:04

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:02:22

US3042264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:02:22

US3042264

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:13
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:08
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:13
User entered '15 Oct 2020'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:08
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:22
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:17
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:22
User entered '15 Oct 2020'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:17
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:22
User entered '08:12'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:17
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
User entered '15 Oct 2020 08:12'	(b) (4), (b) (6) System	15 Oct 2020 15:40:17

US3042264

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:23:31
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Oct 2020 15:40:18
	(b) (4)	

US3042264

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:02:22
User entered '1'	(b) (4), (b) (6) System	15 Oct 2020 15:40:18

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 64'	System	20 Aug 2020 21:10:15

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-10-20T07:05:37', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'cc25ef5c-343c-4313-b3b3-d873ebff4532'	(b) (4), (b) (6)	20 Oct 2020 12:05:57
User entered 'No (N)'	System	20 Oct 2020 12:05:57

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-10-20T07:05:44', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'cc25ef5c-343c-4313-b3b3-d873ebff4532'	(b) (4), (b) (6)	20 Oct 2020 12:05:57
User entered 'No (N)'	System	20 Oct 2020 12:05:57

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-10-20T07:05:56', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'cc25ef5c-343c-4313-b3b3-d873ebff4532' User entered '20 Oct 2020 07:05:56'	(b) (4), (b) (6) System	20 Oct 2020 12:05:57
	System	20 Oct 2020 12:05:57

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 21:10:15

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 21:10:15

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 71'	System	20 Aug 2020 21:10:15

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-10-28T11:34:42', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f0f7b8a9-f356-4f6f-9624-c80117f8a3d9'	(b) (4), (b) (6)	
	System	28 Oct 2020 16:35:32
User entered 'Yes (Y)'	System	28 Oct 2020 16:35:32

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-10-28T11:34:47', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f0f7b8a9-f356-4f6f-9624-c80117f8a3d9'	(b) (4), (b) (6) System	28 Oct 2020 16:35:32
User entered 'No (N)'	System	28 Oct 2020 16:35:32

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-10-28T11:34:51', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f0f7b8a9-f356-4f6f-9624-c80117f8a3d9'	(b) (4), (b) (6) System	28 Oct 2020 16:35:32
User entered 'No (N)'	System	28 Oct 2020 16:35:32

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-10-28T11:35:05', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f0f7b8a9-f356-4f6f-9624-c80117f8a3d9'	(b) (4), (b) (6)	28 Oct 2020 16:35:32
User entered 'Yes (Y)'	System	28 Oct 2020 16:35:32

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-10-28T11:35:13', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f0f7b8a9-f356-4f6f-9624-c80117f8a3d9'	(b) (4), (b) (6) System	28 Oct 2020 16:35:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Oct 2020 16:35:32

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-10-28T11:35:21', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f0f7b8a9-f356-4f6f-9624-c80117f8a3d9'	(b) (4), (b) (6)	
	System	28 Oct 2020 16:35:32
User entered '28 Oct 2020 11:35:21'	System	28 Oct 2020 16:35:32

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 21:10:15

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 21:10:15

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 78'	System	20 Aug 2020 21:10:15

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-11-06T06:41:04', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '59e2f9c8-00bf-4c9d-98f3-319b771fee54'	(b) (4), (b) (6)	
	System	06 Nov 2020 12:41:17
User entered 'No (N)'	System	06 Nov 2020 12:41:17

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-11-06T06:41:10', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '59e2f9c8-00bf-4c9d-98f3-319b771fee54'	(b) (4), (b) (6)	
	System	06 Nov 2020 12:41:17
User entered 'No (N)'	System	06 Nov 2020 12:41:17

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-11-06T06:41:14', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '59e2f9c8-00bf-4c9d-98f3-319b771fee54'	(b) (4), (b) (6)	
	System	06 Nov 2020 12:41:17
User entered '06 Nov 2020 06:41:14'	System	06 Nov 2020 12:41:17

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 21:10:15

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 21:10:15

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered 'Day 92'	System	20 Aug 2020 21:10:15

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-11-17T08:26:06', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'fe6a6403-0d48-427c-a964-d4b6bfb8f68a'	(b) (4), (b) (6)	17 Nov 2020 14:26:18
User entered 'No (N)'	System	17 Nov 2020 14:26:18

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-11-17T08:26:11', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'fe6a6403-0d48-427c-a964-d4b6bfb8f68a'	(b) (4), (b) (6)	17 Nov 2020 14:26:18
User entered 'No (N)'	System	17 Nov 2020 14:26:18

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-11-17T08:26:15', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'fe6a6403-0d48-427c-a964-d4b6bfb8f68a'	(b) (4), (b) (6) System	17 Nov 2020 14:26:18
User entered '17 Nov 2020 08:26:15'	System	17 Nov 2020 14:26:18

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 21:10:15

US3042264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:56:52
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 21:10:15
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 21:10:15

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2020-11-23T14:17:08', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '923bdfaa-c563-46e4-abdf-de7122a9e219'	System	23 Nov 2020 20:17:27
User entered 'No (N)'	System	23 Nov 2020 20:17:27

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2020-11-23T14:17:17', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '923bdfaa-c563-46e4-abdf-de7122a9e219'	System	23 Nov 2020 20:17:27
User entered 'No (N)'	System	23 Nov 2020 20:17:27

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-11-23T14:17:21', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '923bdfaa-c563-46e4-abdf-de7122a9e219' User entered '23 Nov 2020 14:17:21'	System	23 Nov 2020 20:17:27
	System	23 Nov 2020 20:17:27

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2020-11-30T19:32:22', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '6b4ada26-0c0d-48a8-841f-b36f67939651'	System	01 Dec 2020 01:32:39
User entered 'No (N)'	System	01 Dec 2020 01:32:39

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2020-11-30T19:32:33', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '6b4ada26-0c0d-48a8-841f-b36f67939651'	System	01 Dec 2020 01:32:39
User entered 'No (N)'	System	01 Dec 2020 01:32:39

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-11-30T19:32:37', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '6b4ada26-0c0d-48a8-841f-b36f67939651'	System	01 Dec 2020 01:32:39
User entered '30 Nov 2020 19:32:37'	System	01 Dec 2020 01:32:39

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2020-12-05T00:28:45', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '8ffe821c-d731-476e-962e-11deb9ac57ef'	System	05 Dec 2020 06:28:58
User entered 'No (N)'	System	05 Dec 2020 06:28:58

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2020-12-05T00:28:51', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '8ffe821c-d731-476e-962e-11deb9ac57ef'	System	05 Dec 2020 06:28:58
User entered 'No (N)'	System	05 Dec 2020 06:28:58

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-12-05T00:28:56', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '8ffe821c-d731-476e-962e-11deb9ac57ef' User entered '05 Dec 2020 00:28:56'	System	05 Dec 2020 06:28:58
	System	05 Dec 2020 06:28:58

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2020-12-12T00:02:32', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'c1a7f483-e2fe-40e9-8443-1ff61037d70e'	System	12 Dec 2020 06:02:49
User entered 'No (N)'	System	12 Dec 2020 06:02:49

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2020-12-12T00:02:43', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'c1a7f483-e2fe-40e9-8443-1ff61037d70e'	System	12 Dec 2020 06:02:49
User entered 'No (N)'	System	12 Dec 2020 06:02:49

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-12-12T00:02:45', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'c1a7f483-e2fe-40e9-8443-1ff61037d70e'	System	12 Dec 2020 06:02:49
User entered '12 Dec 2020 00:02:45'	System	12 Dec 2020 06:02:49

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2020-12-19T10:26:49', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '09da81ff-6fae-4eb9-b778-f4db98969bf1'	System	19 Dec 2020 16:26:59
User entered 'No (N)'	System	19 Dec 2020 16:26:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2020-12-19T10:26:54', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '09da81ff-6fae-4eb9-b778-f4db98969bf1'	System	19 Dec 2020 16:26:59
User entered 'No (N)'	System	19 Dec 2020 16:26:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-12-19T10:26:58', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '09da81ff-6fae-4eb9-b778-f4db98969bf1' User entered '19 Dec 2020 10:26:58'	System	19 Dec 2020 16:26:59
	System	19 Dec 2020 16:26:59

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2020-12-27T09:15:49', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '176c89e7-866d-471a-a153-086b2f49624c'	System	27 Dec 2020 15:16:00
User entered 'No (N)'	System	27 Dec 2020 15:16:00

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2020-12-27T09:15:52', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '176c89e7-866d-471a-a153-086b2f49624c'	System	27 Dec 2020 15:16:00
User entered 'No (N)'	System	27 Dec 2020 15:16:00

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2020-12-27T09:15:56', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '176c89e7-866d-471a-a153-086b2f49624c' User entered '27 Dec 2020 09:15:56'	System	27 Dec 2020 15:16:00
	System	27 Dec 2020 15:16:00

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-01-02T08:52:50', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '166858dc-a4dd-4c0f-8787-7ff2ddc0636e'	System	02 Jan 2021 14:53:00
User entered 'No (N)'	System	02 Jan 2021 14:53:00

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-01-02T08:52:54', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '166858dc-a4dd-4c0f-8787-7ff2ddc0636e'	System	02 Jan 2021 14:53:00
User entered 'No (N)'	System	02 Jan 2021 14:53:00

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-01-02T08:52:59', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '166858dc-a4dd-4c0f-8787-7ff2ddc0636e' User entered '02 Jan 2021 08:52:59'	System	02 Jan 2021 14:53:00
	System	02 Jan 2021 14:53:00

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-01-09T00:25:55', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e026f0f8-6dda-4224-ab7d-92f784888884'	System	09 Jan 2021 06:26:14
User entered 'No (N)'	System	09 Jan 2021 06:26:14

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-01-09T00:26:04', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e026f0f8-6dda-4224-ab7d-92f784888884'	System	09 Jan 2021 06:26:14
User entered 'No (N)'	System	09 Jan 2021 06:26:14

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-01-09T00:26:08', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e026f0f8-6dda-4224-ab7d-92f784888884' User entered '09 Jan 2021 00:26:08'	System	09 Jan 2021 06:26:14
	System	09 Jan 2021 06:26:14

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-01-16T06:08:14', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e63e851f-e764-4a2c-99cb-074f2a10207c'	System	16 Jan 2021 12:08:27
User entered 'No (N)'	System	16 Jan 2021 12:08:27

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-01-16T06:08:21', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e63e851f-e764-4a2c-99cb-074f2a10207c'	System	16 Jan 2021 12:08:27
User entered 'No (N)'	System	16 Jan 2021 12:08:27

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-01-16T06:08:26', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e63e851f-e764-4a2c-99cb-074f2a10207c'	System	16 Jan 2021 12:08:27
User entered '16 Jan 2021 06:08:26'	System	16 Jan 2021 12:08:27

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-01-23T00:13:33', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f4dd6f64-3f22-4ec1-b9ad-a85aacf71bc'	System	23 Jan 2021 06:13:48
User entered 'No (N)'	System	23 Jan 2021 06:13:48

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-01-23T00:13:38', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f4dd6f64-3f22-4ec1-b9ad-a85aacf71bc'	System	23 Jan 2021 06:13:48
User entered 'No (N)'	System	23 Jan 2021 06:13:48

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-01-23T00:13:44', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'f4dd6f64-3f22-4ec1-b9ad-a85aacaf71bc' User entered '23 Jan 2021 00:13:44'	System	23 Jan 2021 06:13:48
	System	23 Jan 2021 06:13:48

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-01-30T09:02:02', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'fc46c468-0e30-4378-aef8-7047b42462d4'	System	30 Jan 2021 15:02:11
User entered 'No (N)'	System	30 Jan 2021 15:02:11

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-01-30T09:02:05', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'fc46c468-0e30-4378-aef8-7047b42462d4'	System	30 Jan 2021 15:02:11
User entered 'No (N)'	System	30 Jan 2021 15:02:11

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-01-30T09:02:09', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'fc46c468-0e30-4378-aef8-7047b42462d4'	System	30 Jan 2021 15:02:11
User entered '30 Jan 2021 09:02:09'	System	30 Jan 2021 15:02:11

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-02-06T10:01:45', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'a77daa53-e9a4-42d3-9b25-291421154b7b'	System	06 Feb 2021 16:01:58
User entered 'No (N)'	System	06 Feb 2021 16:01:58

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-02-06T10:01:52', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'a77daa53-e9a4-42d3-9b25-291421154b7b'	System	06 Feb 2021 16:01:58
User entered 'No (N)'	System	06 Feb 2021 16:01:58

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-02-06T10:01:56', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'a77daa53-e9a4-42d3-9b25-291421154b7b'	System	06 Feb 2021 16:01:58
User entered '06 Feb 2021 10:01:56'	System	06 Feb 2021 16:01:58

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-02-13T08:45:51', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '737fc74d-94bd-454d-b0cc-71fb9b7373b8'	System	13 Feb 2021 14:46:01
User entered 'No (N)'	System	13 Feb 2021 14:46:01

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-02-13T08:45:55', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '737fc74d-94bd-454d-b0cc-71fb9b7373b8'	System	13 Feb 2021 14:46:01
User entered 'No (N)'	System	13 Feb 2021 14:46:01

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-02-13T08:45:58', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '737fc74d-94bd-454d-b0cc-71fb9b7373b8' User entered '13 Feb 2021 08:45:58'	System	13 Feb 2021 14:46:01
	System	13 Feb 2021 14:46:01

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-02-20T20:50:48', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '90e04f36-6886-4d12-8afd-6ebd08fadf8a'	System	21 Feb 2021 02:51:05
User entered 'No (N)'	System	21 Feb 2021 02:51:05

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-02-20T20:50:52', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '90e04f36-6886-4d12-8afd-6ebd08fadf8a'	System	21 Feb 2021 02:51:05
User entered 'No (N)'	System	21 Feb 2021 02:51:05

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-02-20T20:51:00', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '90e04f36-6886-4d12-8afd-6ebd08fadf8a'	System	21 Feb 2021 02:51:05
User entered '20 Feb 2021 20:51:00'	System	21 Feb 2021 02:51:05

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-02-27T00:30:49', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2eb933f9-6314-447f-852c-3a95f099e5ef'	System	27 Feb 2021 06:31:02
User entered 'No (N)'	System	27 Feb 2021 06:31:02

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-02-27T00:30:53', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2eb933f9-6314-447f-852c-3a95f099e5ef'	System	27 Feb 2021 06:31:02
User entered 'No (N)'	System	27 Feb 2021 06:31:02

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-02-27T00:30:58', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2eb933f9-6314-447f-852c-3a95f099e5ef' User entered '27 Feb 2021 00:30:58'	System	27 Feb 2021 06:31:02
	System	27 Feb 2021 06:31:02

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-03-06T01:22:42', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'aeff9f84-5bb5-476e-b322-333d46776f62'	System	06 Mar 2021 07:23:00
User entered 'No (N)'	System	06 Mar 2021 07:23:00

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-03-06T01:22:51', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'aeff9f84-5bb5-476e-b322-333d46776f62'	System	06 Mar 2021 07:23:00
User entered 'No (N)'	System	06 Mar 2021 07:23:00

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-03-06T01:22:55', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'aeff9f84-5bb5-476e-b322-333d46776f62'	System	06 Mar 2021 07:23:00
User entered '06 Mar 2021 01:22:55'	System	06 Mar 2021 07:23:00

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-03-13T09:06:44', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b7331ccd-44a2-45ef-b2a7-20100e1d5c97'	System	13 Mar 2021 15:06:56
User entered 'No (N)'	System	13 Mar 2021 15:06:56

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-03-13T09:06:48', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b7331ccd-44a2-45ef-b2a7-20100e1d5c97'	System	13 Mar 2021 15:06:56
User entered 'No (N)'	System	13 Mar 2021 15:06:56

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-03-13T09:06:51', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'b7331ccd-44a2-45ef-b2a7-20100e1d5c97'	System	13 Mar 2021 15:06:56
User entered '13 Mar 2021 09:06:51'	System	13 Mar 2021 15:06:56

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-03-20T11:07:45', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'bea7baee-8f8c-4c69-bb44-b2a14baf8aee'	System	20 Mar 2021 16:13:40
User entered 'No (N)'	System	20 Mar 2021 16:13:40

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-03-20T11:07:49', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'bea7baee-8f8c-4c69-bb44-b2a14baf8aee'	System	20 Mar 2021 16:13:40
User entered 'No (N)'	System	20 Mar 2021 16:13:40

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-03-20T11:07:52', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'bea7baee-8f8c-4c69-bb44-b2a14baf8aee' User entered '20 Mar 2021 11:07:52'	System	20 Mar 2021 16:13:40
	System	20 Mar 2021 16:13:40

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-03-27T07:52:53', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'a9fabcf3-3b39-414c-9032-3acdb5d93839'	System	27 Mar 2021 12:53:04
User entered 'No (N)'	System	27 Mar 2021 12:53:04

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-03-27T07:52:56', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'a9fabcf3-3b39-414c-9032-3acdb5d93839'	System	27 Mar 2021 12:53:04
User entered 'No (N)'	System	27 Mar 2021 12:53:04

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-03-27T07:52:59', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'a9fabcf3-3b39-414c-9032-3acdb5d93839' User entered '27 Mar 2021 07:52:59'	System	27 Mar 2021 12:53:04
	System	27 Mar 2021 12:53:04

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-04-03T00:05:23', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e7a3e292-a0c9-4724-a012-99a08da19241'	System	03 Apr 2021 05:05:39
User entered 'No (N)'	System	03 Apr 2021 05:05:39

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-04-03T00:05:27', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e7a3e292-a0c9-4724-a012-99a08da19241'	System	03 Apr 2021 05:05:39
User entered 'No (N)'	System	03 Apr 2021 05:05:39

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-04-03T00:05:31', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: 'e7a3e292-a0c9-4724-a012-99a08da19241'	System	03 Apr 2021 05:05:39
User entered '03 Apr 2021 00:05:31'	System	03 Apr 2021 05:05:39

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-04-10T08:15:56', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '7af06bce-6ede-4ed2-a5e9-f2f5de33b3fc'	System	10 Apr 2021 13:16:09
User entered 'No (N)'	System	10 Apr 2021 13:16:09

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-04-10T08:15:58', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '7af06bce-6ede-4ed2-a5e9-f2f5de33b3fc'	System	10 Apr 2021 13:16:09
User entered 'No (N)'	System	10 Apr 2021 13:16:09

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-04-10T08:16:04', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '7af06bce-6ede-4ed2-a5e9-f2f5de33b3fc'	System	10 Apr 2021 13:16:09
User entered '10 Apr 2021 08:16:04'	System	10 Apr 2021 13:16:09

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-04-17T07:43:54', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2587099f-3af7-4383-b61f-3030ca3a2e31'	System	17 Apr 2021 12:44:07
User entered 'No (N)'	System	17 Apr 2021 12:44:07

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-04-17T07:43:59', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2587099f-3af7-4383-b61f-3030ca3a2e31'	System	17 Apr 2021 12:44:07
User entered 'No (N)'	System	17 Apr 2021 12:44:07

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-04-17T07:44:02', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2587099f-3af7-4383-b61f-3030ca3a2e31'	System	17 Apr 2021 12:44:07
User entered '17 Apr 2021 07:44:02'	System	17 Apr 2021 12:44:07

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-04-24T01:37:04', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2f0e33e7-c85b-437f-bf80-e5496292061b'	System	24 Apr 2021 06:37:29
User entered 'No (N)'	System	24 Apr 2021 06:37:29

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-04-24T01:37:07', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2f0e33e7-c85b-437f-bf80-e5496292061b'	System	24 Apr 2021 06:37:29
User entered 'No (N)'	System	24 Apr 2021 06:37:29

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-04-24T01:37:23', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '2f0e33e7-c85b-437f-bf80-e5496292061b' User entered '24 Apr 2021 01:37:23'	System	24 Apr 2021 06:37:29
	System	24 Apr 2021 06:37:29

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[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 (89ccc4cc47438a9a)', Time: '2021-05-01T12:39:17-05:00', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '994d882a-f5f0-418e-8e07-81ed64d055d7'	System	01 May 2021 17:39:26
User entered 'No (N)'	System	01 May 2021 17:39:26

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

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 (89ccc4cc47438a9a)', Time: '2021-05-01T12:39:19-05:00', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '994d882a-f5f0-418e-8e07-81ed64d055d7'	System	01 May 2021 17:39:26
User entered 'No (N)'	System	01 May 2021 17:39:26

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-05-01T12:39:23-05:00', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '994d882a-f5f0-418e-8e07-81ed64d055d7'	System	01 May 2021 17:39:26
User entered '01 May 2021 12:39:23'	System	01 May 2021 17:39:26

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:14:17

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:14:17

US3042264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:14:17
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:14:17

US3042264

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:56:50

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 12:44:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-03-01T11:06:37', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '3b2d5642-89f8-4a39-ac40-d3488ab8c924'	System	01 Mar 2021 17:19:50
User entered 'No (N)'	System	01 Mar 2021 17:19:50

US3042264

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:56:50

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:44:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (89ccc4cc47438a9a)', Time: '2021-03-01T11:06:44', User OID: 'PatientReportedOutcome (US3042264)', ODM File OID: '3b2d5642-89f8-4a39-ac40-d3488ab8c924'	System	01 Mar 2021 17:19:50
User entered '01 Mar 2021 11:06:44'	System	01 Mar 2021 17:19:50

US3042264

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:20
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:24:03
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:13:30

US3042264

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:20
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:24:03
User entered '10 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:13:30

US3042264

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:20
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:24:03
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:13:30

US3042264

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:20
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:24:03
User entered empty.	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:13:30

US3042264

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:20
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:24:12
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	11 Dec 2020 20:13:33

US3042264

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:22:20
User entered 'I'	System	11 Dec 2020 20:13:33

US3042264

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:51
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4)	16 Apr 2021 16:24:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 17:57:32

US3042264

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:51
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:24:27
User entered '15 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 17:57:32

US3042264

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:51
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:24:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Dec 2020 17:57:32

US3042264

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:51
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:24:27
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 17:57:32

US3042264

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:51
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:24:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 17:57:38

US3042264

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:31:51
User entered 'I'	System	15 Dec 2020 17:57:38

US3042264

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:38
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:24:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Jan 2021 18:32:18

US3042264

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:38
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:24:51
User entered '12 Jan 2021'	(b) (4), (b) (6)	12 Jan 2021 18:32:18

US3042264

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:38
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:24:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Jan 2021 18:32:18

US3042264

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:38
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:24:51
User entered empty.	(b) (4), (b) (6)	12 Jan 2021 18:32:18

US3042264

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:38
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:24:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Jan 2021 18:32:24

US3042264

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:16:38
User entered 'I'	System	12 Jan 2021 18:32:24

US3042264

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:47:02
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 21:45:12

US3042264

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:47:02
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:10
User entered '11 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 21:45:12

US3042264

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:47:02
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Feb 2021 21:45:12

US3042264

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:47:02
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:25:10
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 21:45:12

US3042264

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:47:02
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 21:45:17

US3042264

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:47:02
User entered 'I'	System	11 Feb 2021 21:45:17

US3042264

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:33
User entered 'Yes (Y)'	(b) (4) Jessica Knight (b) (4) (b) (4)	02 Mar 2021 21:29:07

US3042264

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:33
User entered '02 Mar 2021'	(b) (4) Jessica Knight (b) (4) (b) (4)	02 Mar 2021 21:29:07

US3042264

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:33
User entered 'Clinic (Clinic)'	(b) (4) Jessica Knight (b) (4) (b) (4)	02 Mar 2021 21:29:07

US3042264

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User entered 'VISIT4'	(b) (4), (b) (6) System	02 Mar 2021 21:29:07

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:42
User entered 'No (N)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:42
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:42
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:42
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:42
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:42
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:42
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:42
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:42
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:42
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 18:00:25

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:50:24

US3042264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:50:24

US3042264

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:52
User entered 'No (N)'	(b) (4) Jessica Knight (b) (4) (b) (4)	02 Mar 2021 21:29:14

US3042264

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:25:52
User entered empty.	(b) (4) Jessica Knight (b) (4) (b) (4)	02 Mar 2021 21:29:14

US3042264

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:26:01
User entered 'Yes (Y)'	(b) (4) Jessica Knight (b) (4) (b) (4)	02 Mar 2021 21:29:30

US3042264

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:26:01
User entered '02 Mar 2021'	(b) (4) Jessica Knight (b) (4) (b) (4)	02 Mar 2021 21:29:30

US3042264

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:26:01
User entered '11:27'	(b) (4) Jessica Knight (b) (4) (b) (4)	02 Mar 2021 21:29:30

US3042264

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User entered '02 Mar 2021 11:27'	(b) (4), (b) (6) System	02 Mar 2021 21:29:30

US3042264

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:26:10
User entered 'Yes (Y)'	(b) (4) Jessica Knight (b) (4) (b) (4)	02 Mar 2021 21:29:36

US3042264

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:24
User entered 'I'	(b) (4), (b) (6) System	02 Mar 2021 21:29:36

US3042264

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:26:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 19:33:04

US3042264

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:26:26
User entered '14 Apr 2021'	(b) (4), (b) (6)	14 Apr 2021 19:33:04

US3042264

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:26:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Apr 2021 19:33:04

US3042264

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:26:26
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 19:33:04

US3042264

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:26:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 19:32:54

US3042264

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 19:32:54

US3042264

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

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:00
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:24
	(b) (4)	

US3042264

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

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:00
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:24
	(b) (4)	

US3042264

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

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:00
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:24
	(b) (4)	

US3042264

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

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	13 Jan 2021 16:22:24

US3042264

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

Form: Unblinding

Generated On: 09 Jun 2021 14:56:50

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:09
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:31
	(b) (4)	

US3042264

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

Form: Unblinding

Generated On: 09 Jun 2021 14:56:50

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:09
User entered '0'	Rylea Gulick (b) (4)	08 Apr 2021 18:39:39
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:22:46

US3042264

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

Form: Unblinding

Generated On: 09 Jun 2021 14:56:50

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:09
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:31
	(b) (4)	

US3042264

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

Form: Unblinding

Generated On: 09 Jun 2021 14:56:50

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:27:09
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:49:09
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	08 Apr 2021 18:39:43
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rylea Gulick (b) (4) (b) (4)	08 Apr 2021 18:39:39
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:07:46
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:22:46

US3042264

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

Form: Unblinding

Generated On: 09 Jun 2021 14:56:50

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:09
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:31
	(b) (4)	

US3042264

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

Form: Unblinding

Generated On: 09 Jun 2021 14:56:50

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:09
User entered 'Placebo (Placebo)'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:31
	(b) (4)	

US3042264

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

Form: Unblinding

Generated On: 09 Jun 2021 14:56:50

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:09
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:55:52
User entered 'Placebo (Placebo)'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:31
	(b) (4)	

US3042264

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

Form: Unblinding

Generated On: 09 Jun 2021 14:56:50

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:09
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:55:52
User entered 'Placebo (Placebo)'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:31
	(b) (4)	

US3042264

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

Form: Unblinding

Generated On: 09 Jun 2021 14:56:50

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:09
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:31
	(b) (4)	

US3042264

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

Form: Unblinding

Generated On: 09 Jun 2021 14:56:50

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered '1'	(b) (4), (b) (6) System	13 Jan 2021 16:22:31

US3042264

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

Form: Unblinding

Generated On: 09 Jun 2021 14:56:50

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered 'I'	(b) (4), (b) (6) System	13 Jan 2021 16:22:31

US3042264

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered missing code ND - Not Done.	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered missing code ND - Not Done.	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User entered empty.	System	13 Jan 2021 16:24:09
DataPoint set to visible.	System	13 Jan 2021 16:22:31

US3042264

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered missing code ND - Not Done.	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered missing code ND - Not Done.	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User entered empty.	System	13 Jan 2021 16:24:09
DataPoint set to visible.	System	13 Jan 2021 16:22:31

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '08:46'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered '13 Jan 2021 08:46'	(b) (4), (b) (6)	
	System	13 Jan 2021 16:24:09

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '36.6' C	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '64'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered 'bpm'	(b) (4), (b) (6) System	13 Jan 2021 16:24:09

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '12'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered 'breaths/min'	(b) (4), (b) (6) System	13 Jan 2021 16:24:09

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '112'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 16:24:09

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered 'mmHg'	(b) (4), (b) (6) System	13 Jan 2021 16:24:09

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '68'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered 'mmHg'	(b) (4), (b) (6) System	13 Jan 2021 16:24:09

US3042264

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered missing code ND - Not Done.	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered missing code ND - Not Done.	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User entered empty.	System	13 Jan 2021 16:24:09
DataPoint set to visible.	System	13 Jan 2021 16:22:31

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '09:42'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered '13 Jan 2021 09:42'	(b) (4), (b) (6)	
	System	13 Jan 2021 16:24:09

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '36.6' C	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered empty.	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '62'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered 'bpm'	(b) (4), (b) (6) System	13 Jan 2021 16:24:09

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '12'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered 'breaths/min'	(b) (4), (b) (6) System	13 Jan 2021 16:24:09

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '110'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 16:24:09

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered 'mmHg'	(b) (4), (b) (6) System	13 Jan 2021 16:24:09

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:20
User entered '70'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:09
	(b) (4)	

US3042264

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered 'mmHg'	(b) (4), (b) (6) System	13 Jan 2021 16:24:09

US3042264

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:31
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:24
	(b) (4)	

US3042264

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:31
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:24
	(b) (4)	

US3042264

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

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:39
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:37
	(b) (4)	

US3042264

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

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:39
User entered empty.	Rylea Gulick (b) (4)	13 Jan 2021 16:24:37
	(b) (4)	

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

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:39
User entered empty.	Rylea Gulick (b) (4)	13 Jan 2021 16:24:37
	(b) (4)	

US3042264

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

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User entered 'mRNA-1273'	System	13 Jan 2021 16:24:37
DataPoint set to visible.	System	13 Jan 2021 16:22:31

US3042264

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

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:39
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:37
	(b) (4)	

US3042264

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

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:39
User entered '09:02'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:37
	(b) (4)	

US3042264

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

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered '13 Jan 2021 09:02'	(b) (4), (b) (6)	
	System	13 Jan 2021 16:24:37

US3042264

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

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:39
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4)	13 Jan 2021 16:24:37
	(b) (4)	

US3042264

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

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 16:27:39
User entered 'ONCE'	System	13 Jan 2021 16:24:37

US3042264

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

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	13 Jan 2021 16:24:37

US3042264

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:50
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:38
	(b) (4)	

US3042264

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:50
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:38
	(b) (4)	

US3042264

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:50
User entered '08:22'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:38
	(b) (4)	

US3042264

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered '13 Jan 2021 08:22'	(b) (4), (b) (6)	
	System	13 Jan 2021 16:22:38

US3042264

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:56:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:59
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:44
	(b) (4)	

US3042264

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:59
User entered '13 Jan 2021'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:44
	(b) (4)	

US3042264

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:27:59
User entered '08:31'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:44
	(b) (4)	

US3042264

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:03
User entered '13 Jan 2021 08:31'	(b) (4), (b) (6)	
	System	13 Jan 2021 16:22:44

US3042264

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

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:16
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	13 Jan 2021 16:22:46
	(b) (4)	

US3042264

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

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:58:27
User entered 'I'	(b) (4), (b) (6) System	13 Jan 2021 16:22:46

US3042264

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:46
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:28:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	01 Apr 2021 19:08:47
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:39:26

US3042264

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:46
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:28:29
User entered '20 Jan 2021' reason for change: Data Entry Error	Jamie Thompson (b) (4)	01 Apr 2021 19:08:47
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:39:26

US3042264

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:46
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:28:29
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Jamie Thompson (b) (4) (b) (4)	01 Apr 2021 19:08:47
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:39:26

US3042264

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:46
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:28:29
User entered empty.	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:39:26

US3042264

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:46
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:28:38
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:39:29

US3042264

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:46
User entered 'I'	System	17 Feb 2021 16:39:29

US3042264

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:46
User entered '1'	System	17 Feb 2021 16:39:29
DataPoint set to visible.	System	17 Feb 2021 16:39:29

US3042264

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:53
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Feb 2021 16:39:55
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:53
User entered '17 Feb 2021'	Rylea Gulick (b) (4)	17 Feb 2021 16:39:55
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:28:53
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	17 Feb 2021 16:39:55
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered 'OLD29'	(b) (4), (b) (6) System	17 Feb 2021 16:39:55

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Feb 2021 16:40:51
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '17 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '08:12'	Rylea Gulick (b) (4)	17 Feb 2021 16:40:51
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered '17 Feb 2021 08:12'	(b) (4), (b) (6) System	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '36.8' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	17 Feb 2021 16:40:51
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered empty.	Rylea Gulick (b) (4)	17 Feb 2021 16:40:51
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '73'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered 'bpm'	(b) (4), (b) (6) System	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '12'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '116'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered 'mmHg'	(b) (4), (b) (6) System	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '82'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered 'mmHg'	(b) (4), (b) (6) System	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Feb 2021 16:40:51
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '17 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '09:00'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered '17 Feb 2021 09:00'	(b) (4), (b) (6) System	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '36.6' C	Rylea Gulick (b) (4)	17 Feb 2021 16:40:51
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	17 Feb 2021 16:40:51
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered empty.	Rylea Gulick (b) (4)	17 Feb 2021 16:40:51
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '75'	Rylea Gulick (b) (4)	17 Feb 2021 16:40:51
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered 'bpm'	(b) (4), (b) (6) System	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '12'	Rylea Gulick (b) (4)	17 Feb 2021 16:40:51
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '132'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered 'mmHg'	(b) (4), (b) (6) System	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:01
User entered '80'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered 'mmHg'	(b) (4), (b) (6) System	17 Feb 2021 16:40:51

US3042264

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:12
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Feb 2021 16:40:54
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:12
User entered '17 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:40:54

US3042264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:21
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:41:36

US3042264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:21
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:41:36

US3042264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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)	30 Apr 2021 04:15:29
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:21
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	17 Feb 2021 16:41:36

US3042264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered 'mRNA-1273'	(b) (4), (b) (6)	
	System	17 Feb 2021 16:41:36
DataPoint set to visible.	System	17 Feb 2021 16:39:29

US3042264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:21
User entered '17 Feb 2021'	Rylea Gulick (b) (4)	17 Feb 2021 16:41:36
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:21
User entered '08:28'	Rylea Gulick (b) (4)	17 Feb 2021 16:41:36
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered '17 Feb 2021 08:28'	(b) (4), (b) (6) System	17 Feb 2021 16:41:36

US3042264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:21
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4)	17 Feb 2021 16:41:36
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:21
User entered 'ONCE'	System	17 Feb 2021 16:41:36

US3042264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	17 Feb 2021 16:41:36

US3042264

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:29:33
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	17 Feb 2021 16:41:40
	(b) (4)	

US3042264

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:29
User entered 'I'	(b) (4), (b) (6) System	17 Feb 2021 16:41:40

US3042264

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:45:53
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:46
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	24 Feb 2021 16:09:19

US3042264

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:45:53
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:46
User entered '24 Feb 2021'	Jamie Thompson (b) (4) (b) (4)	24 Feb 2021 16:09:19

US3042264

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:45:53
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:46
User entered 'Contact Made (CONTACT MADE)'	Jamie Thompson (b) (4) (b) (4)	24 Feb 2021 16:09:19

US3042264

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:45:53
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:46
User entered empty.	Jamie Thompson (b) (4) (b) (4)	24 Feb 2021 16:09:19

US3042264

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:45:53
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:29:55
User entered 'Yes (Y)'	Jamie Thompson (b) (4) (b) (4)	24 Feb 2021 16:09:23

US3042264

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:45:53
User entered 'I'	System	24 Feb 2021 16:09:23

US3042264

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:08
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 13:59:45

US3042264

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:08
User entered '16 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 13:59:45

US3042264

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:08
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 13:59:45

US3042264

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User entered 'OLD57'	(b) (4), (b) (6) System	16 Mar 2021 13:59:45

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:17
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:17
User entered '16 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:17
User entered '08:05'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User entered '16 Mar 2021 08:05'	(b) (4), (b) (6) System	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:17
User entered '37.0' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:17
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:17
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:17
User entered '66'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User entered 'bpm'	(b) (4), (b) (6) System	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:17
User entered '12'	Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:17
User entered '130'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User entered 'mmHg'	(b) (4), (b) (6) System	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:17
User entered '82'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User entered 'mmHg'	(b) (4), (b) (6) System	16 Mar 2021 14:00:00

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
	(b) (4), (b) (6)	

US3042264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:50

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
	(b) (4), (b) (6)	

US3042264

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:31
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:15

US3042264

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:31
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:15

US3042264

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:38
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:22

US3042264

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:38
User entered '16 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:22

US3042264

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:30:38
User entered '08:20'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Mar 2021 14:00:22

US3042264

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:46
User entered '16 Mar 2021 08:20'	(b) (4), (b) (6) System	16 Mar 2021 14:00:22

US3042264

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:12:49
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:01:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 16:52:29
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:14

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:33
User entered	System	29 Oct 2020 15:00:28
'USA-US052-2020-mRNA-1273-P301000013'		
User entered 'New'	(b) (4), (b) (6)	29 Oct 2020 15:00:28

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
User closed query 'PV Query: As per the query response, the subject has the event of three ruptured discs in lumbar spine chronically. Could you please confirm if the subject have a medical history of ruptured discs in lumbar spine? Was the SAE considered a worsening of the subject's medical history of ruptured discs in lumbar spine ?' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:35:32
Query 'PV Query: As per the query response, the subject has the event of three ruptured discs in lumbar spine chronically. Could you please confirm if the subject have a medical history of ruptured discs in lumbar spine? Was the SAE considered a worsening of the subject's medical history of ruptured discs in lumbar spine ?' answered with 'SUBJECT HAS NO MEDICAL HISTORY OF RUPTURED DISCS.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 22:20:22
User opened query 'PV Query: As per the query response, the subject has the event of three ruptured discs in lumbar spine chronically. Could you please confirm if the subject have a medical history of ruptured discs in lumbar spine? Was the SAE considered a worsening of the subject's medical history of ruptured discs in lumbar spine ?' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:09:03
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:11:38
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: Ruptured intervertebral disc - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:13:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:13:27
Data point term sent to Coder	System	28 Oct 2020 16:55:43
User entered '3 RUPTURED DISCS IN LUMBAR SPINE'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered '26 Oct 2020'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered empty.	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:45:33
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 18:29:15
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 18:29:15
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:45:34
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	15 Dec 2020 18:29:29
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	15 Dec 2020 18:29:29
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	15 Dec 2020 18:29:15
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 18:29:15
User entered '07 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 18:29:15
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:25:40
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Ongoing' (Site from Safety).	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:37:47
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:33:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:11:38
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:50:58

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'will be updated when available' (Site from Safety).	Rylea Gulick (b) (4)	07 Nov 2020 15:01:12
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:03:23
User entered empty.	Rylea Gulick (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered empty.	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 22:28:37
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 14:21:34
User entered empty.	System	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

Severity

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
User closed query 'Per DM CLR: Please review Severity of Grade 1/Mild as it was noted on the Narrative field, this AE was persistent or significant disability or incapacity. Please review and update as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review Severity of Grade 1/Mild as it was noted on the Narrative field, this AE was persistent or significant disability or incapacity. Please review and update as appropriate. Otherwise, clarify.' answered with 'Grade 1' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 11:17:07
User opened query 'Per DM CLR: Please review Severity of Grade 1/Mild as it was noted on the Narrative field, this AE was persistent or significant disability or incapacity. Please review and update as appropriate. Otherwise, clarify.'	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:38:04
User opened query 'Per DM CLR: Please review Severity of Grade 1/Mild as it was noted on the Narrative field, this AE was persistent or significant disability or incapacity. Please review and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 12:43:09
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4. (Query has been closed. No treatment/intervention was provided). ' canceled (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:37:28
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4. (Query has been closed. No treatment/intervention was provided). ' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:34:41
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:11:38
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 22:10:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 22:10:50
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:10:50
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 16:55:25
User entered empty.	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered '0'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered '0'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered '26 Oct 2020'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered '28 Oct 2020'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered empty.	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered '0'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered '0'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered '0'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered 'Not Related (NOT RELATED)'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:33:28
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 06:59:46
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:39:35
' answered with 'Corrected' (Site from DM).		
DataPoint Un-verified.	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:39:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:39:26
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:14:28
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

None

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 22:56:36
User closed query 'In progress note pain meds are mentioned yet not recorded on con med page and none is marked here, please verify. If progress note in source is incorrect, please update and correct with additional info as to why. Thanks.	(b) (4), (b) (6)	27 Apr 2021 22:56:21
' (Site from CRA). Query 'In progress note pain meds are mentioned yet not recorded on con med page and none is marked here, please verify. If progress note in source is incorrect, please update and correct with additional info as to why. Thanks.	Rylea Gulick (b) (4) (b) (4)	27 Apr 2021 21:38:19
' answered with 'PAIN MEDS ARE UNKNOWN' (Site from CRA). User opened query 'In progress note pain meds are mentioned yet not recorded on con med page and none is marked here, please verify. If progress note in source is incorrect, please update and correct with additional info as to why. Thanks.	(b) (4), (b) (6)	16 Apr 2021 17:02:36
' (Site from CRA). Query 'In progress not pain meds are mentioned yet not recorded on con med page and none is marked here, please verify.' canceled (Site from CRA). User opened query 'In progress not pain meds are mentioned yet not recorded on con med page and none is marked here, please verify.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 17:00:46 16 Apr 2021 16:47:15 16 Apr 2021 16:46:19
User closed query 'Per CDM, CLR re-query: Response as following up with patient is noted, however please review and update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 06:50:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

None

Audit	User	Time (GMT)
Query 'Per CDM, CLR re-query: Response as following up with patient is noted, however please review and update accordingly. Otherwise clarify. Thank you.' answered with 'SUBJECT REPORTED THAT THERE WERE NO MEDICATION CHANGES OR PROCEDURES BEING DONE.' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:21:42
User opened query 'Per CDM, CLR re-query: Response as following up with patient is noted, however please review and update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:21:42
User closed query 'Per DM CLR: Please verify if there were treatments given for this SAE as treatments are expected for SAEs. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment is needed.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:18:26
Query 'Per DM CLR: Please verify if there were treatments given for this SAE as treatments are expected for SAEs. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment is needed.' answered with 'Following up with pt' (Site from DM).	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:40:43
User opened query 'Per DM CLR: Please verify if there were treatments given for this SAE as treatments are expected for SAEs. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment is needed.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 12:44:21
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered '0'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered '0'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

US3042264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:47:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 18:29:29
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 20:35:45
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'ENTRY WILL BE UPDATED WHEN AVAILABLE, HOWEVER, PER SITE, QUERY CANNOT BE OPEN MORE THAN 24 HOURS.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 22:21:32
DataPoint Un-verified.	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 22:21:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	09 Dec 2020 22:21:12
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 21:07:53
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 19:27:19
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'this is still recovering/resolving. subject has this chronically.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:28:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 14:21:52
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:25:46
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Following up with pt' (Site from Safety).	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:40:52
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:33:31
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:11:38
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:51:16
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'will be updated when available' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	07 Nov 2020 15:01:25
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:03:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:11:38
User entered empty.	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 22:57:40
User closed query 'There is no discharge summary in source and no documentation available other than a progress note. Please provide additional documentation if possible.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 22:57:25
Query 'There is no discharge summary in source and no documentation available other than a progress note. Please provide additional documentation if possible.' answered with 'ENTRY UPDATED WITH MORE DESCRIPTION' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	27 Apr 2021 21:40:52
User entered 'ADMITTED TO HOSPITAL FOR PAIN CONTROL AND TESTING. IMAGING WAS PERFORMED. NO SURGERY OR MED CHANGES.' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	27 Apr 2021 21:39:41
User opened query 'There is no discharge summary in source and no documentation available other than a progress note. Please provide additional documentation if possible.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:50:55
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:49:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:47:40
User closed query 'PV Query: Please confirm patient receive no treatment for ruptured discs in lumbar spine. ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 19:27:24
User closed query 'PV Query: What was the underlying etiology/cause of ruptured discs in lumbar spine (e.g. fall, injury, etc) ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 19:27:23
User closed query 'PV Query: The narrative reports "persistent or significant disability or incapacity". Please clarify if this disability should be added as seriousness criteria, and further explain the disability. ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 19:27:21
Query 'PV Query: The narrative reports "persistent or significant disability or incapacity". Please clarify if this disability should be added as seriousness criteria, and further explain the disability. ' answered with 'ENTRY HAS BEEN UPDATED' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	02 Dec 2020 20:31:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Rylea Gulick (b) (4)	02 Dec 2020 20:31:43
	(b) (4)	
User entered 'HOSPITALIZATION OCCURED.' reason for change: Data Entry Error	Rylea Gulick (b) (4)	02 Dec 2020 20:31:43
	(b) (4)	
Query 'PV Query: What was the underlying etiology/cause of ruptured discs in lumbar spine (e.g. fall, injury, etc) ' answered with 'there is no underlying etiology.' (Site from Safety).	Rylea Gulick (b) (4)	02 Dec 2020 20:27:50
	(b) (4)	
Query 'PV Query: Please confirm patient receive no treatment for ruptured discs in lumbar spine. ' answered with 'SUBJECT DID NOT RECIEVE A TREATMENT FOR RUPTURED DISCS.' (Site from Safety).	Rylea Gulick (b) (4)	02 Dec 2020 20:22:41
	(b) (4)	
User opened query 'PV Query: Please confirm patient receive no treatment for ruptured discs in lumbar spine. ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 14:22:56
User opened query 'PV Query: What was the underlying etiology/cause of ruptured discs in lumbar spine (e.g. fall, injury, etc) ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 14:22:45
User opened query 'PV Query: The narrative reports "persistent or significant disability or incapacity". Please clarify if this disability should be added as seriousness criteria, and further explain the disability. ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 14:22:20
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Response: There is no relevant lab or diagnostic tests provided' canceled (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:34:25
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:34:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Response: currently no treatment is being given' canceled (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:34:16
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:33:57
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Response: currently no treatment is being given' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:33:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Response: There is no relevant lab or diagnostic tests provided' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 18:33:43
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:11:38
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)	09 Nov 2020 19:51:41

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:51:38
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:51:27
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 'NO RESULTS TO REPORT' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	07 Nov 2020 15:02:58
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'currently no treatment is being given' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	07 Nov 2020 15:02:22
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'there is no relevant lab or diagnostic tests provided' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	07 Nov 2020 15:01:53
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)	05 Nov 2020 17:04:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:03:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:03:49
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Nov 2020 22:10:50
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	04 Nov 2020 22:10:50
User entered 'PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	04 Nov 2020 22:10:50
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Oct 2020 16:55:25
User entered empty.	Rylea Gulick (b) (4) (b) (4)	28 Oct 2020 16:55:25

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 16:55:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 16:55:25

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 16:55:25

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:12:49
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:26
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:28:04

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:37:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:37:12
Data point term sent to Coder	System	21 Aug 2020 00:36:44
User entered 'SUCRALFATE'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'PEPTIC ULCER'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'g (g)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:35:47
User entered 'UN UNK 2010'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 00:35:47

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: GEMFIBROZIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:18:37
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 Nov 2020 21:18:37
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	12 Nov 2020 21:17:37 12 Nov 2020 21:17:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: GEMFIBROZIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 05:14:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 05:14:18
Data point term sent to Coder User entered 'GEMFIBROZIE'	System Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:45 21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'HYPERLIPIDEMIA'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '600'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:36:27
User entered 'UN UNK 2005'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 00:36:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:18:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:18:40
Data point term sent to Coder	System	12 Nov 2020 21:17:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:17:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 01:14:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 01:14:52
Data point term sent to Coder	System	14 Sep 2020 14:12:21
Coding entries removed.	Rylea Gulick (b) (4)	14 Sep 2020 14:11:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 05:16:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 05:16:10
Data point term sent to Coder	System	21 Aug 2020 00:37:45
User entered 'GABAPENTIN'	Rylea Gulick (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User closed query 'Per DM CLR: Please update the indication and clarify the type of the BILATERAL FOOT NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:00:47
Query 'Per DM CLR: Please update the indication and clarify the type of the BILATERAL FOOT NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 14:11:29
User entered 'BILATERAL FOOT NEUROPATHY-SENSORY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 14:11:23
User opened query 'Per DM CLR: Please update the indication and clarify the type of the BILATERAL FOOT NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 06:07:22
User entered 'BILATERAL FOOT NEUROPATHY'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '800'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:08
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:37:01
User entered 'UN UNK 2010'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 00:37:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
User closed query 'Per CDM CLR re-query: Response noted; however, the Con-med#3 and Con-med#4 both are overlapping. Please review if both the entries are needed or else remove one of the duplicate entries from Con-med. Otherwise clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 07:55:26
Query 'Per CDM CLR re-query: Response noted; however, the Con-med#3 and Con-med#4 both are overlapping. Please review if both the entries are needed or else remove one of the duplicate entries from Con-med. Otherwise clarify. Thank you.' answered with 'Correct per pt chart' (Site from DM).	Jessica Knight (b) (4) (b) (4)	22 Nov 2020 16:36:59
User opened query 'Per CDM CLR re-query: Response noted; however, the Con-med#3 and Con-med#4 both are overlapping. Please review if both the entries are needed or else remove one of the duplicate entries from Con-med. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:14:59
User closed query 'Per DM CLR: Please review the dates of ConMed #s 3 and 4 as both medications were noted as ongoing and have overlapping dates. Please reconcile and update so there is no overlap or provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:09:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:18:37
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 Nov 2020 21:18:37
Data point term sent to Coder	System	12 Nov 2020 21:17:38
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:17:37

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

Name of Medication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the dates of ConMed #s 3 and 4 as both medications were noted as ongoing and have overlapping dates. Please reconcile and update so there is no overlap or provide clarification.' answered with 'dates are correct' (Site from DM).	Rylea Gulick (b) (4)	01 Oct 2020 20:32:16
User opened query 'Per DM CLR: Please review the dates of ConMed #s 3 and 4 as both medications were noted as ongoing and have overlapping dates. Please reconcile and update so there is no overlap or provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 06:54:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 01:14:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 01:14:52
Data point term sent to Coder Coding entries removed.	System	14 Sep 2020 14:12:21
	Rylea Gulick (b) (4)	14 Sep 2020 14:11:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 05:16:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 05:16:10
Data point term sent to Coder	System	21 Aug 2020 00:37:46
User entered 'GABAPENTIN'	Rylea Gulick (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User closed query 'Per DM CLR: Please update the indication and clarify the type of the BILATERAL FOOT NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:00:58
Query 'Per DM CLR: Please update the indication and clarify the type of the BILATERAL FOOT NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 14:11:43
User entered 'BILATERAL FOOT NEUROPATHY-SENSORY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 14:11:38
User opened query 'Per DM CLR: Please update the indication and clarify the type of the BILATERAL FOOT NEUROPATHY (i.e. sensory or motor). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 06:06:44
User entered 'BILATERAL FOOT NEUROPATHY'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '600'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:37:39
User entered 'UN UNK 2010'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 00:37:39

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:18:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:18:38
Data point term sent to Coder DataPoint Verified.	System	12 Nov 2020 21:17:38
	(b) (4), (b) (6)	12 Nov 2020 21:17:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 00:39:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 00:39:23
Data point term sent to Coder User entered 'ATORVASTATIN'	System	21 Aug 2020 00:38:46
	Rylea Gulick (b) (4)	21 Aug 2020 00:38:22
	(b) (4)	

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'HYPERLIPIDEMIA'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '40'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:38:22
User entered 'UN UNK 2005'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 00:38:22

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:18:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:18:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	12 Nov 2020 21:17:38 12 Nov 2020 21:17:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 00:40:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 00:40:23
Data point term sent to Coder User entered 'OMEPRAZOLE'	System Rylea Gulick (b) (4)	21 Aug 2020 00:39:47 21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'ACID REFLUX'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '20'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'twice daily (BID)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:06
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:39:02
User entered 'UN UNK 2010'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 00:39:02

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Nov 2020 21:18:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:18:35
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	12 Nov 2020 21:17:41 12 Nov 2020 21:17:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 00:40:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 00:40:23
Data point term sent to Coder User entered 'METFORMIN'	System Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:47 21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'DIABETES TYPE 2'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '500'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:39:27
User entered 'UN UNK 1993'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 00:39:27

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Nov 2020 21:18:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:18:38
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	12 Nov 2020 21:17:39 12 Nov 2020 21:17:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:41:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:41:28
Data point term sent to Coder User entered 'HYDROCHLOROTHIAZIDE'	System Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:47 21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'HYPERTENSION'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '25'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:39:53
User entered 'UN UNK 1995'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 00:39:53

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
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)	12 Nov 2020 21:18:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:18:38
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	12 Nov 2020 21:17:41 12 Nov 2020 21:17:37
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)	21 Aug 2020 00:41:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 00:41:28
Data point term sent to Coder User entered 'LISINOPRIL'	System Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:49 21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'HYPERTENSION'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
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) (6)	22 Sep 2020 07:38:23
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 'THIS IS THE DOSAGE SUBJECT REPORTS TAKING' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 14:12:52
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) (b) (4), (b) (6)	14 Sep 2020 06:04:15
User entered '25'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:28
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:40:20
User entered 'UN UNK 1995'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 00:40:20

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
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)	12 Nov 2020 21:18:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:18:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	12 Nov 2020 21:17:41 12 Nov 2020 21:17:37
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)	21 Aug 2020 00:42:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 00:42:28
Data point term sent to Coder User entered 'TAMSULOSIN'	System Rylea Gulick (b) (4)	21 Aug 2020 00:41:50 21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'BENIGN PROSTATIC HYPERPLASIA'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '.4'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:40:50
User entered 'UN UNK 2015'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 00:40:50

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:18:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:18:36
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	12 Nov 2020 21:17:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 00:42:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 00:42:29
Data point term sent to Coder User entered 'GLIMEPIRIDE'	System Rylea Gulick (b) (4)	21 Aug 2020 00:41:50
	(b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'DIABETES TYPE 2'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '2'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:41:24
User entered 'UN UNK 2000'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 00:41:24

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:18:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 21:18:39
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	12 Nov 2020 21:17:41 12 Nov 2020 21:17:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:53:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 13:53:39
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4)	14 Sep 2020 14:14:25 14 Sep 2020 14:13:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 05:25:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 05:25:15
Data point term sent to Coder User entered 'HYDROCODONE/ACETAMINOPHEN'	System Rylea Gulick (b) (4)	21 Aug 2020 00:42:52 21 Aug 2020 00:42:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Query 'Per DM CLR: Please review Indication and please update to specify the location of Osteoarthritis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 10:11:41
User opened query 'Per DM CLR: Please review Indication and please update to specify the location of Osteoarthritis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 06:55:11
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:01:32
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'ENTRY UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 14:13:40
User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	14 Sep 2020 14:13:36
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Sep 2020 06:03:24
User entered 'ARTHRITIS'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '2.5/500'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:03:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ALL MEDICATION ONGOING' (Site from System).	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:06
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	21 Aug 2020 00:42:01
User entered 'UN UNK 2015'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered '0'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered empty.	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:17:37
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 00:42:01

US3042264

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:56:50

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:01:45
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	21 Aug 2020 00:42:11

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'USA-US052-2020-MRNA-1273-P301000013'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:34
User closed query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:39:33
Query 'Please update again with PI's name, thanks.' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Apr 2021 19:11:15
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User opened query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:32:08
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Meagan'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
	(b) (4), (b) (6)	
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:39:59
	(b) (4), (b) (6)	
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:19
	(b) (4)	
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
User entered 'David' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
	(b) (4), (b) (6)	
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:12
	(b) (4), (b) (6)	

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EAB) (1725)

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Meagan'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:36
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:14
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Miller'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:40:10
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:26
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
User entered 'Enszt' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:34
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Miller'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
User closed query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:06:49
Query 'Please enter address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:52
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User opened query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:23:22
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '330 dakota dunes suite400'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'North sioux'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'IA'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '57049'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:18:47
User entered 'US'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '8'	System	28 Apr 2021 12:52:25
User entered '7'	System	15 Dec 2020 21:28:08
User entered '6'	System	10 Dec 2020 20:38:41
User entered '5'	System	03 Dec 2020 19:27:38
User entered '4'	System	23 Nov 2020 14:26:13
User entered '3'	System	09 Nov 2020 19:31:57
User entered '2'	System	05 Nov 2020 16:18:56
User entered '1'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'USA-US052-2020-MRNA-1273-P301000013'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:34
User closed query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:39:33
Query 'Please update again with PI's name, thanks.' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Apr 2021 19:11:15
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User opened query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:32:08
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:03
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Meagan'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:05
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:39:59
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:19
	(b) (4)	
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
User entered 'David' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:12

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EAB) (1725)

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Meagan'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:36
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:14
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Miller'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:40:10
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:26
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
User entered 'Enszt' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:34
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Miller'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
User closed query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:06:49
Query 'Please enter address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:52
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User opened query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:23:22
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '330 dakota dunes suite400'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'North sioux'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'IA'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '57049'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:18:47
User entered 'US'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '8'	System	28 Apr 2021 12:52:25
User entered '7'	System	15 Dec 2020 21:28:08
User entered '6'	System	10 Dec 2020 20:38:41
User entered '5'	System	03 Dec 2020 19:27:38
User entered '4'	System	23 Nov 2020 14:26:13
User entered '3'	System	09 Nov 2020 19:31:57
User entered '2'	System	05 Nov 2020 16:18:56
User entered '1'	System	29 Oct 2020 15:00:58

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
User entered '29/Oct/2020 11:00'	System	29 Oct 2020 15:00:58

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:18:47
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'USA-US052-2020-MRNA-1273-P301000013'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

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Form: Safety Report Form

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Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:34
User closed query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:39:33
Query 'Please update again with PI's name, thanks.' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Apr 2021 19:11:15
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User opened query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:32:08
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Meagan'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
	(b) (4), (b) (6)	
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:39:59
	(b) (4), (b) (6)	
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:19
	(b) (4)	
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
User entered 'David' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
	(b) (4), (b) (6)	
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:12
	(b) (4), (b) (6)	

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EAB) (1725)

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Meagan'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:36
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:14
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Miller'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:40:10
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:26
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
User entered 'Enszt' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:34
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Miller'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
User closed query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:06:49
Query 'Please enter address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:52
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User opened query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:23:22
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '330 dakota dunes suite400'	System	29 Oct 2020 15:00:28

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Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'North sioux'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'IA'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '57049'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:18:47
User entered 'US'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '8'	System	28 Apr 2021 12:52:25
User entered '7'	System	15 Dec 2020 21:28:08
User entered '6'	System	10 Dec 2020 20:38:41
User entered '5'	System	03 Dec 2020 19:27:38
User entered '4'	System	23 Nov 2020 14:26:13
User entered '3'	System	09 Nov 2020 19:31:57
User entered '2'	System	05 Nov 2020 16:18:56
User entered '1'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
User entered '05/Nov/2020 11:18'	System	05 Nov 2020 16:18:56

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 14:26:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 16:18:56

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'USA-US052-2020-MRNA-1273-P301000013'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:34
User closed query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:39:33
Query 'Please update again with PI's name, thanks.' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Apr 2021 19:11:15
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User opened query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:32:08
	(b) (4), (b) (6)	16 Apr 2021 16:31:03
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:03
	(b) (4), (b) (6)	17 Dec 2020 17:47:11
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Meagan'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
	(b) (4), (b) (6)	
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:05
	(b) (4), (b) (6)	24 Nov 2020 05:39:59
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:39:59
	(b) (4), (b) (6)	
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:19
	(b) (4)	
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
User entered 'David' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
	(b) (4), (b) (6)	
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:12
	(b) (4), (b) (6)	

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EAB) (1725)

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Meagan'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:36
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:14
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Miller'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:40:10
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:26
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
User entered 'Enszt' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:34
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Miller'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
User closed query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:06:49
Query 'Please enter address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:52
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User opened query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:23:22
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '330 dakota dunes suite400'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'North sioux'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'IA'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '57049'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:18:47
User entered 'US'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '8'	System	28 Apr 2021 12:52:25
User entered '7'	System	15 Dec 2020 21:28:08
User entered '6'	System	10 Dec 2020 20:38:41
User entered '5'	System	03 Dec 2020 19:27:38
User entered '4'	System	23 Nov 2020 14:26:13
User entered '3'	System	09 Nov 2020 19:31:57
User entered '2'	System	05 Nov 2020 16:18:56
User entered '1'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
User entered '09/Nov/2020 14:31'	System	09 Nov 2020 19:31:57

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 14:26:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 19:31:57

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'USA-US052-2020-MRNA-1273-P301000013'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:34
User closed query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:39:33
Query 'Please update again with PI's name, thanks.' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Apr 2021 19:11:15
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User opened query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:32:08
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:03
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Meagan'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:05
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:39:59
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:19
	(b) (4)	
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
User entered 'David' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:12

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EAB) (1725)

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Meagan'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:36
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:14
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Miller'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:40:10
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:26
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
User entered 'Enszt' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:34
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Miller'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
User closed query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:06:49
Query 'Please enter address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:52
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User opened query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:23:22
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '330 dakota dunes suite400'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'North sioux'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'IA'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '57049'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:18:47
User entered 'US'	System	29 Oct 2020 15:00:58

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '8'	System	28 Apr 2021 12:52:25
User entered '7'	System	15 Dec 2020 21:28:08
User entered '6'	System	10 Dec 2020 20:38:41
User entered '5'	System	03 Dec 2020 19:27:38
User entered '4'	System	23 Nov 2020 14:26:13
User entered '3'	System	09 Nov 2020 19:31:57
User entered '2'	System	05 Nov 2020 16:18:56
User entered '1'	System	29 Oct 2020 15:00:58

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:51:42
User entered '23/Nov/2020 09:26'	System	23 Nov 2020 14:26:13

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Form: Safety Report Form (4)

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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.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:51:42
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 14:26:13

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'USA-US052-2020-MRNA-1273-P301000013'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:34
User closed query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:39:33
Query 'Please update again with PI's name, thanks.' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Apr 2021 19:11:15
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User opened query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:32:08
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Meagan'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
	(b) (4), (b) (6)	
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:39:59
	(b) (4), (b) (6)	
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:19
	(b) (4)	
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
User entered 'David' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
	(b) (4), (b) (6)	
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:12
	(b) (4), (b) (6)	

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Meagan'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:36
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:14
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Miller'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:40:10
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:26
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
User entered 'Enszt' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:34
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Miller'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
User closed query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:06:49
Query 'Please enter address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:52
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User opened query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:23:22
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '330 dakota dunes suite400'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'North sioux'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'IA'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '57049'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:18:47
User entered 'US'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '8'	System	28 Apr 2021 12:52:25
User entered '7'	System	15 Dec 2020 21:28:08
User entered '6'	System	10 Dec 2020 20:38:41
User entered '5'	System	03 Dec 2020 19:27:38
User entered '4'	System	23 Nov 2020 14:26:13
User entered '3'	System	09 Nov 2020 19:31:57
User entered '2'	System	05 Nov 2020 16:18:56
User entered '1'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:51:42
User entered '03/Dec/2020 19:27'	System	03 Dec 2020 19:27:38

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:51:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
User entered 'I'	(b) (4), (b) (6)	03 Dec 2020 19:27:38

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'USA-US052-2020-MRNA-1273-P301000013'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:34
User closed query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:39:33
Query 'Please update again with PI's name, thanks.' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Apr 2021 19:11:15
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User opened query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:32:08
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Meagan'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
	(b) (4), (b) (6)	
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:39:59
	(b) (4), (b) (6)	
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:19
	(b) (4)	
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
User entered 'David' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
	(b) (4), (b) (6)	
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:12
	(b) (4), (b) (6)	

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EAB) (1725)

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Meagan'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:36
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:14
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Miller'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:40:10
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:26
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
User entered 'Enszt' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:34
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Miller'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
User closed query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:06:49
Query 'Please enter address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:52
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User opened query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:23:22
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '330 dakota dunes suite400'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'North sioux'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'IA'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '57049'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:18:47
User entered 'US'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User entered '8'	System	28 Apr 2021 12:52:25
User entered '7'	System	15 Dec 2020 21:28:08
User entered '6'	System	10 Dec 2020 20:38:41
User entered '5'	System	03 Dec 2020 19:27:38
User entered '4'	System	23 Nov 2020 14:26:13
User entered '3'	System	09 Nov 2020 19:31:57
User entered '2'	System	05 Nov 2020 16:18:56
User entered '1'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:51:42
User entered '10/Dec/2020 12:38'	System	10 Dec 2020 20:38:41

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:51:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
User entered 'I'	(b) (4), (b) (6)	10 Dec 2020 20:38:41

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'USA-US052-2020-MRNA-1273-P301000013'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:34
User closed query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:39:33
Query 'Please update again with PI's name, thanks.' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Apr 2021 19:11:15
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User opened query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:32:08
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Meagan'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
	(b) (4), (b) (6)	
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:39:59
	(b) (4), (b) (6)	
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:19
	(b) (4)	
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
User entered 'David' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
	(b) (4), (b) (6)	
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:12
	(b) (4), (b) (6)	

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EAB) (1725)

US3042264

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Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Meagan'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:36
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:14
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Miller'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:40:10
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:26
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
User entered 'Enszt' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:34
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Miller'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
User closed query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:06:49
Query 'Please enter address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:52
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User opened query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:23:22
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '330 dakota dunes suite400'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'North sioux'	System	29 Oct 2020 15:00:28

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Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'IA'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '57049'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:18:47
User entered 'US'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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

Audit	User	Time (GMT)
User entered '8'	System	28 Apr 2021 12:52:25
User entered '7'	System	15 Dec 2020 21:28:08
User entered '6'	System	10 Dec 2020 20:38:41
User entered '5'	System	03 Dec 2020 19:27:38
User entered '4'	System	23 Nov 2020 14:26:13
User entered '3'	System	09 Nov 2020 19:31:57
User entered '2'	System	05 Nov 2020 16:18:56
User entered '1'	System	29 Oct 2020 15:00:58

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:51:42
User entered '15/Dec/2020 16:28'	System	15 Dec 2020 21:28:08

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 17:51:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:31:17
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 21:28:08

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'USA-US052-2020-MRNA-1273-P301000013'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Yes (Y)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

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Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'No (N)'	System	29 Oct 2020 15:00:28

US3042264

Folder: SAE USA-US052-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:34
User closed query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:39:33
Query 'Please update again with PI's name, thanks.' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4)	16 Apr 2021 19:11:15
	(b) (4)	
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
	(b) (4)	
User opened query 'Please update again with PI's name, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:32:08
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Meagan'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
	(b) (4), (b) (6)	
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:39:59
	(b) (4), (b) (6)	
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:19
	(b) (4)	
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
User entered 'David' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
	(b) (4), (b) (6)	
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:12
	(b) (4), (b) (6)	

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EAB) (1725)

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Meagan'	System	29 Oct 2020 15:00:28

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 12:51:59
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:39:36
Un-reviewed for Safety.	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4)	16 Apr 2021 19:10:49
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:31:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:47:14
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 21:27:52
Un-reviewed for Safety.	System	03 Dec 2020 19:27:38
DataPoint Un-verified.	System	03 Dec 2020 19:27:38
User entered 'Miller'	System	03 Dec 2020 19:27:38
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 19:27:30
User closed query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 05:40:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 05:40:10
Query 'Should be PI's name, thanks' answered with 'updated' (Site from CRA).	Jessica Knight (b) (4)	24 Nov 2020 00:02:26
Un-reviewed for Safety.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Un-verified.	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
User entered 'Enszt' reason for change: Data Entry Error	Jessica Knight (b) (4)	24 Nov 2020 00:02:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
User opened query 'Should be PI's name, thanks' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:59:34
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'Miller'	System	29 Oct 2020 15:00:28

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Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
User closed query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:06:49
Query 'Please enter address, thanks' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:52
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User opened query 'Please enter address, thanks' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 17:23:22
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '330 dakota dunes suite400'	System	29 Oct 2020 15:00:28

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Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:50

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'North sioux'	System	29 Oct 2020 15:00:28

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Form: Safety Report Form

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[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered 'IOWA' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered 'IA'	System	29 Oct 2020 15:00:28

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	03 May 2021 17:31:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:07:12
Signature has been broken.	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	29 Apr 2021 18:40:30
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 21:36:51
Un-reviewed for Safety.	System	28 Apr 2021 12:52:25
DataPoint Un-verified.	System	28 Apr 2021 12:52:25
User entered empty.	System	28 Apr 2021 12:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:00:50
User entered '57049'	System	29 Oct 2020 15:00:28

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Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:00:48
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:18:47
User entered 'US'	System	29 Oct 2020 15:00:58

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Form: Safety Report Form

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

Audit	User	Time (GMT)
User entered '8'	System	28 Apr 2021 12:52:25
User entered '7'	System	15 Dec 2020 21:28:08
User entered '6'	System	10 Dec 2020 20:38:41
User entered '5'	System	03 Dec 2020 19:27:38
User entered '4'	System	23 Nov 2020 14:26:13
User entered '3'	System	09 Nov 2020 19:31:57
User entered '2'	System	05 Nov 2020 16:18:56
User entered '1'	System	29 Oct 2020 15:00:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:07:12
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
User entered '28/Apr/2021 08:52'	(b) (4) System	28 Apr 2021 12:52:25

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Form: Safety Report Form (8)

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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)	29 Apr 2021 21:07:12
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 21:36:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 12:52:25