

US3042203 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:57:51

All time stamps listed in this document are displayed in GMT

US3042203

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

Participant ID

US3042203

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

US3042203

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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 10:23:17

Generated On: 09 Jun 2021 14:57:51

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
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 10:23:17

Generated On: 09 Jun 2021 14:57:51

Date of Informed Consent (<i>dd MMM yyyy</i>)	14 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 10:23:17

Generated On: 09 Jun 2021 14:57:51

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 10:23:17

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Condition	LEFT CHEST NEUROPATHY
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
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 10:23:17

Generated On: 09 Jun 2021 14:57:51

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
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 10:23:17

Generated On: 09 Jun 2021 14:57:51

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
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 10:23:17

Generated On: 09 Jun 2021 14:57:51

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Condition	RIGHT LUNG BULLAS
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Condition	LEFT LUNG BULLAS
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Condition	LEFT PARTIAL LOBECTOMY
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3042203

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:20 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 13:20
Height (<i>xxx.x</i>)	177.8 cm
Weight (<i>xxx.x</i>)	90 kg
BMI (<i>xxx.x</i>)	28.46944 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 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 10:23:17

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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

GOES TO GAS STATIONS
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 10:23:17

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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 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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 10:23:17

Generated On: 09 Jun 2021 14:57:51

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

What was the participant's randomization number? 143913

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 10:23:17

Generated On: 09 Jun 2021 14:57:51

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 10:23:17

Generated On: 09 Jun 2021 14:57:51

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 13:20
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)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 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 10:23:17

Generated On: 09 Jun 2021 14:57:51

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)	14 AUG 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 15:09
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 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 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

US3042203

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 14:32 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 14:32

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 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	14:08 (24 HR)
Collection date and time (derived)	14 AUG 2020 14:08

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:01	14 AUG 2020 14:01
Nasopharyngeal Swab 2	No		

US3042203

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 15:04

PC Open Date & Time

14 AUG 2020 14:52

PC Close Date & Time

14 AUG 2020 17:22

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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 98.8 °F

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

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

PC Time Stamp	14 AUG 2020 18:53
PC Open Date & Time	14 AUG 2020 18:17
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

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

97.6 °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

15 AUG 2020 12:04

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

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

16 AUG 2020 16:53

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 16:25

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 16:19

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

99.1 °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 AUG 2020 15:41

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

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

98.1 °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 19:36

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 15:02

PC Open Date & Time

14 AUG 2020 14:52

PC Close Date & Time

14 AUG 2020 17:22

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

14 AUG 2020 18:54

PC Open Date & Time

14 AUG 2020 18:17

PC Close Date & Time

15 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

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

15 AUG 2020 12:04

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

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

16 AUG 2020 16:53

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

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

17 AUG 2020 16:25

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

18 AUG 2020 16:19

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

19 AUG 2020 15:41

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

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

20 AUG 2020 19:37

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 15:04
PC Open Date & Time	14 AUG 2020 14:52
PC Close Date & Time	14 AUG 2020 17:22

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 18:54
PC Open Date & Time	14 AUG 2020 18:17
PC Close Date & Time	15 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

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 ☒

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 12:06
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

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)

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 16:54
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

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 ☒

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 16:26
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

56 of 2175

EAB) (1725)

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 16:20
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 15:42
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

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 ☒

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 19:37
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3042203

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

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)	11 SEP 2020
Time of assessment (00:00-23:59)	14:51 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:51
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

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)	11 SEP 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 16:05
Temperature (xxx.x)	37.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3042203

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3042203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 15:31 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 15:31

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

US3042203

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

15:13 (24 HR)

Collection date and time (derived)

11 SEP 2020 15:13

US3042203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:06	11 SEP 2020 15:06
Nasopharyngeal Swab 2	No		

US3042203

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

99.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 16:02

PC Open Date & Time

11 SEP 2020 15:51

PC Close Date & Time

11 SEP 2020 18:21

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

98.9 °F

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

Yes ☐
No ☒

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

PC Time Stamp	11 SEP 2020 20:22
PC Open Date & Time	11 SEP 2020 19:16
PC Close Date & Time	12 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

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

12 SEP 2020 21:58

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 18:58

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 18:54

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

15 SEP 2020 19:48

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 15:58

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

11 SEP 2020 16:03

PC Open Date & Time

11 SEP 2020 15:51

PC Close Date & Time

11 SEP 2020 18:21

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

11 SEP 2020 20:22

PC Open Date & Time

11 SEP 2020 19:16

PC Close Date & Time

12 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

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

12 SEP 2020 21:58

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

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

13 SEP 2020 18:59

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

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

14 SEP 2020 18:55

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

15 SEP 2020 19:49

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

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

17 SEP 2020 15:59

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 16:04
PC Open Date & Time	11 SEP 2020 15:51
PC Close Date & Time	11 SEP 2020 18:21

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 20:23
PC Open Date & Time	11 SEP 2020 19:16
PC Close Date & Time	12 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

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 ☒

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 21:58
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 18:59
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:55
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

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 ☒

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 19:49
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

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 ☒

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 16:00
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3042203

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:22:41

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:00 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 13:00
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3042203

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 OCT 2020
Collection time (00:00-23:59)	13:10 (24 HR)
Collection date and time (derived)	16 OCT 2020 13:10

US3042203

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 OCT 2020 13:46:06
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☒

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

21 OCT 2020 09:45:52

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

01 NOV 2020 11:07:29

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

14 NOV 2020 14:10:15

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT	DAY 99
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"/>

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

22 NOV 2020 18:53:37

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	02 DEC 2020 15:57:44
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	09 DEC 2020 09:56:26
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 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	16 DEC 2020 11:07:29
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

21 DEC 2020 10:25:57

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

28 DEC 2020 16:44:47

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	03 JAN 2021 11:56:18
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 <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	10 JAN 2021 12:19:47
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

17 JAN 2021 13:06:48

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	26 JAN 2021 17:44:43
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

01 FEB 2021 15:09:14

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

07 FEB 2021 07:31:14

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 <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	15 FEB 2021 07:12:31
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	21 FEB 2021 15:00:38
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

28 FEB 2021 07:05:46

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

11 MAR 2021 10:11:39

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

16 MAR 2021 17:40:26

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

24 MAR 2021 04:22:25

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

28 MAR 2021 12:30:24

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 APR 2021 17:47:17
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 19:40:42

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

21 APR 2021 18:56:40

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

26 APR 2021 21:15:53

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐ 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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐
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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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°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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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="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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	19 AUG 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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="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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 467

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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="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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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°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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	20 JAN 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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="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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	24 FEB 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 MAR 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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="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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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="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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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°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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	11 AUG 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	14 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐
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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	08 SEP 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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 ☐

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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"/>

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3042203

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:57:51

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		28 FEB 2021 07:06:07

US3042203

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	VISIT4

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

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) _____

US3042203

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

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.

US3042203

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 FEB 2021
Collection time (00:00-23:59)	13:20 (24 HR)
Collection date and time (derived)	26 FEB 2021 13:20

US3042203

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3042203

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:57:51

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"/>

US3042203

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:57:51

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3042203

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

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

Visit date (dd MMM yyyy)	11 JAN 2021
--------------------------	-------------

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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US3042203

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 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>)	11 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

US3042203

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

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

US3042203

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

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)	11 JAN 2021
Time of assessment (00:00-23:59)	14:56 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 14:56
Temperature (xxx.x)	37.2 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3042203

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

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)	11 JAN 2021
Time of assessment (00:00-23:59)	15:56 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 15:56
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)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3042203

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3042203

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

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) 11 JAN 2021

What was the treatment time? (00:00-23:59) 15:18 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 15:18

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

US3042203

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	11 JAN 2021 14:25

US3042203

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	14:32
Collection Date and Time (derived)	11 JAN 2021 14:32

US3042203

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 10:22:39

Generated On: 09 Jun 2021 14:57:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 10:22:39

Generated On: 09 Jun 2021 14:57:51

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)	16 FEB 2021
Time of assessment (00:00-23:59)	13:07 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 13:07
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 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

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 10:22:39

Generated On: 09 Jun 2021 14:57:51

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)	16 FEB 2021
Time of assessment (00:00-23:59)	14:08 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 14:08
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3042203

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:22:39

Generated On: 09 Jun 2021 14:57:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 FEB 2021

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

US3042203

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 10:22:39

Generated On: 09 Jun 2021 14:57:51

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) 16 FEB 2021

What was the treatment time? (00:00-23:59) 13:37 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 13:37

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

US3042203

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:22:39

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3042203

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:23:17

Generated On: 09 Jun 2021 14:57:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3042203

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

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

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:05 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 13:05
Temperature (<i>xxx.x</i>)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	96 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>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3042203

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

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.

US3042203

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	13:12 (24 HR)
Collection date and time (derived)	15 MAR 2021 13:12

US3042203

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

AEID	USA-US052-2020-MRNA-1273-P30 1000022
Adverse event	RIGHT COLLAPSED LUNG
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" 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)	30 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	14 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT WAS HOSPITALIZED FOR A RIGHT COLLAPSED LUNG.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 10:22:39

Generated On: 09 Jun 2021 14:57:51

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

Yes ☒

No ☐

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

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication LEFT SIDE NEUROPATHY

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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US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

	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 2018	
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"/>

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:22:37

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

	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 2018	
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"/>

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

Name of Medication SEREQUEL

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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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 10:22:37

Generated On: 09 Jun 2021 14:57:51

	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 2016	
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"/>

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

Name of Medication SYMBICORT

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 160/4.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

Name of Medication SPIRIVA

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 18

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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 (6)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

	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 APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

Name of Medication TRINTELLIX

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

	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 MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

Name of Medication NABUMETONE

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

	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 2018	
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"/>

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication POST-PROCEDURAL
PAIN-BACK

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 10:22:37

Generated On: 09 Jun 2021 14:57:51

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	14 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3042203

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 10:22:39

Generated On: 09 Jun 2021 14:57:51

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 10:22:39

Generated On: 09 Jun 2021 14:57:51

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 DEC 2020	PLEURODESIS	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:57:51

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 14:57:51

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 ☐

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

SAEID	USA-US052-2020-MRNA-1273-P301000022
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	IA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

SAEID	USA-US052-2020-MRNA-1273-P301000022
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	IA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/DEC/2020 13:03
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

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

SAEID	USA-US052-2020-MRNA-1273-P301000022
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	IA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	06/DEC/2020 16:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

SAEID	USA-US052-2020-MRNA-1273-P301000022
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	IA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/DEC/2020 10:59
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

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

SAEID	USA-US052-2020-MRNA-1273-P301000022
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	IA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/DEC/2020 16:26
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

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

SAEID	USA-US052-2020-MRNA-1273-P301000022
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	IA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/JAN/2021 15:38
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

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 10:22:40

Generated On: 09 Jun 2021 14:57:51

SAEID	USA-US052-2020-MRNA-1273-P301000022
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	IA
Site Address: Postal Code	51106
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/JAN/2021 21:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3042203 (Prod: Meridian Clinical Research)

US3042203

Form: Participant Creation

Generated On: 09 Jun 2021 14:57:51

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
User entered 'US3042203'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 19:14:30

US3042203

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:30:46
	(b) (4)	

US3042203

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '14 AUG 2020'	RWS_ENDPOINT	14 Aug 2020 19:14:31
	ENDPOINT (b) (4)	
	(b) (4)	

US3042203

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:30:46

US3042203

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'SCRN'	(b) (4), (b) (6) System	15 Aug 2020 13:30:46

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered (b) (6) 1961'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 19:14:32

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '59'	Rylea Gulick (b) (4)	15 Aug 2020 13:30:55
	(b) (4)	

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'YEARS'	(b) (4), (b) (6) System	15 Aug 2020 13:30:55

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '59'	(b) (4), (b) (6) System	14 Aug 2020 19:35:12

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Male (M)'	Rylea Gulick (b) (4)	15 Aug 2020 13:30:55
	(b) (4)	

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Rylea Gulick (b) (4)	15 Aug 2020 13:30:55
	(b) (4)	

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'I'	Rylea Gulick (b) (4)	15 Aug 2020 13:30:55
	(b) (4)	

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:30:55
	(b) (4)	

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:30:55
	(b) (4)	

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:30:55
	(b) (4)	

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:30:55
	(b) (4)	

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:30:55
	(b) (4)	

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:30:55
	(b) (4)	

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:30:55
	(b) (4)	

US3042203

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:57:51

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:30:55
	(b) (4)	

US3042203

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:51

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	14 Aug 2020 19:35:12
	(b) (4)	

US3042203

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'Aug 2020'	(b) (4), (b) (6) System	14 Aug 2020 19:35:12

US3042203

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2020'	(b) (4), (b) (6) System	14 Aug 2020 19:35:12

US3042203

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:51

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Amendment 2 (2)'	Rylea Gulick (b) (4)	14 Aug 2020 19:35:12
	(b) (4)	

US3042203

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Aug 2020 19:35:12
	(b) (4)	

US3042203

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:51

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Aug 2020 19:35:12
	(b) (4)	

US3042203

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:51

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Aug 2020 19:35:12
	(b) (4)	

US3042203

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:51

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	14 Aug 2020 19:35:12
	(b) (4)	

US3042203

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:51

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	RWS_ENDPOINT	14 Aug 2020 19:14:31
	ENDPOINT (b) (4)	
	(b) (4)	

US3042203

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:57:51

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'I'	(b) (4), (b) (6) System	14 Aug 2020 19:35:14

US3042203

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Aug 2020 19:35:14
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:57:51

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:04

US3042203

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:05:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:05:53
Data point term sent to Coder	System	18 Aug 2020 16:32:37
Coding entries removed.	Rylea Gulick (b) (4) (b) (4)	18 Aug 2020 16:32:14
User entered 'LEFT CHEST NEUROPATHY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Aug 2020 16:32:14
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Nerve injuries NEC, PT: Nerve injury, LLT: Nerve damage - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 08:50:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 08:50:14
Data point term sent to Coder	System	15 Aug 2020 13:31:25
User entered 'LEFT SIDE NERVE DAMAGE'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:24

US3042203

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'UN UNK 2018'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:24

US3042203

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:24

US3042203

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:24

US3042203

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:31:24
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:24

US3042203

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'Jan 2018'	(b) (4), (b) (6) System	15 Aug 2020 13:31:24

US3042203

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2018'	(b) (4), (b) (6) System	15 Aug 2020 13:31:24

US3042203

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:31:24

US3042203

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:31:24

US3042203

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 13:33:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 13:33:12
	(b) (4)	
Data point term sent to Coder	System	15 Aug 2020 13:32:26
User entered 'HYPERCHOLESTEROLEMIA'	Rylea Gulick (b) (4)	15 Aug 2020 13:31:39
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'UN UNK 2018'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:39

US3042203

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:39

US3042203

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:39

US3042203

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:31:39
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:39

US3042203

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'Jan 2018'	(b) (4), (b) (6) System	15 Aug 2020 13:31:39

US3042203

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2018'	(b) (4), (b) (6) System	15 Aug 2020 13:31:39

US3042203

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:31:39

US3042203

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:31:39

US3042203

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 13:33:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 13:33:12
	(b) (4)	
Data point term sent to Coder	System	15 Aug 2020 13:32:26
User entered 'INSOMNIA'	Rylea Gulick (b) (4)	15 Aug 2020 13:31:47
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'UN UNK 2016'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:47

US3042203

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:47

US3042203

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:47

US3042203

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:31:47
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:31:47

US3042203

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'Jan 2016'	(b) (4), (b) (6) System	15 Aug 2020 13:31:47

US3042203

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2016'	(b) (4), (b) (6) System	15 Aug 2020 13:31:47

US3042203

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:31:47

US3042203

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:31:47

US3042203

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGt: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 13:33:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 13:33:13
	(b) (4)	
Data point term sent to Coder	System	15 Aug 2020 13:32:26
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Rylea Gulick (b) (4)	15 Aug 2020 13:32:12
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'UN UNK 2015'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:12

US3042203

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:12

US3042203

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:12

US3042203

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:32:12
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:12

US3042203

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'Jan 2015'	(b) (4), (b) (6) System	15 Aug 2020 13:32:12

US3042203

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2015'	(b) (4), (b) (6) System	15 Aug 2020 13:32:12

US3042203

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:32:12

US3042203

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:32:12

US3042203

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 13:33:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 13:33:12
	(b) (4)	
Data point term sent to Coder	System	15 Aug 2020 13:32:26
User entered 'SEASONAL ALLERGIES'	Rylea Gulick (b) (4)	15 Aug 2020 13:32:22
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User closed query 'Per CDM: Condition start date = UN UNK 2020. Per CCGs page 22 only conditions that started before the Informed Consent was signed are to be reported on the MH eCRF. Please review and confirm the start date is prior to the Informed consent date, else update as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 10:36:06
Query 'Per CDM: Condition start date = UN UNK 2020. Per CCGs page 22 only conditions that started before the Informed Consent was signed are to be reported on the MH eCRF. Please review and confirm the start date is prior to the Informed consent date, else update as per CCGs. ' answered with 'THIS CONDITION STARTED BEFORE THE SIGNING OF INFORMED CONSENT, HOWEVER, SUBJECT DID NOT NOW WHAT MONTH' (Site from DM).	Rylea Gulick (b) (4)	04 Nov 2020 20:42:03
	(b) (4)	
User opened query 'Per CDM: Condition start date = UN UNK 2020. Per CCGs page 22 only conditions that started before the Informed Consent was signed are to be reported on the MH eCRF. Please review and confirm the start date is prior to the Informed consent date, else update as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:45:22
User entered 'UN UNK 2020'	Rylea Gulick (b) (4)	15 Aug 2020 13:32:22
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:22

US3042203

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:22

US3042203

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:32:22
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:22

US3042203

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'Jan 2020'	(b) (4), (b) (6) System	15 Aug 2020 13:32:22

US3042203

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2020'	(b) (4), (b) (6) System	15 Aug 2020 13:32:22

US3042203

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:32:22

US3042203

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:32:22

US3042203

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Cystic lung disease, LLT: Pulmonary bulla - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 08:11:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 08:11:07
Data point term sent to Coder	System	15 Aug 2020 13:33:28
User entered 'RIGHT LUNG BULLAS'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:42

US3042203

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'UN UNK 2016'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:42

US3042203

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:42

US3042203

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:42

US3042203

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'UN UNK 2016'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:42

US3042203

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:42

US3042203

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'Jan 2016'	(b) (4), (b) (6) System	15 Aug 2020 13:32:42

US3042203

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2016'	(b) (4), (b) (6) System	15 Aug 2020 13:32:42

US3042203

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'Jan 2016'	(b) (4), (b) (6) System	15 Aug 2020 13:32:42

US3042203

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2016'	(b) (4), (b) (6) System	15 Aug 2020 13:32:42

US3042203

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Cystic lung disease, LLT: Pulmonary bulla - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 08:53:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 08:53:15
Data point term sent to Coder	System	15 Aug 2020 13:33:28
User entered 'LEFT LUNG BULLAS'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:56

US3042203

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered 'UN UNK 2018'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:56

US3042203

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:32:56
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:32:56
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered 'UN UNK 2018'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:56

US3042203

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:32:56

US3042203

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'Jan 2018'	(b) (4), (b) (6) System	15 Aug 2020 13:32:56

US3042203

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2018'	(b) (4), (b) (6) System	15 Aug 2020 13:32:56

US3042203

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'Jan 2018'	(b) (4), (b) (6) System	15 Aug 2020 13:32:56

US3042203

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2018'	(b) (4), (b) (6) System	15 Aug 2020 13:32:56

US3042203

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Respiratory tract therapeutic procedures, HLT: Bronchial and pulmonary therapeutic procedures, PT: Pulmonary resection, LLT: Partial lung lobectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 08:51:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Aug 2020 08:51:14
Data point term sent to Coder	System	15 Aug 2020 13:33:29
User entered 'LEFT PARTIAL LOBECTOMY'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:33:13

US3042203

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'UN UNK 2018'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:33:13

US3042203

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:33:13

US3042203

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:33:13

US3042203

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'UN UNK 2018'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:33:13

US3042203

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:33:13

US3042203

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'Jan 2018'	(b) (4), (b) (6) System	15 Aug 2020 13:33:13

US3042203

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2018'	(b) (4), (b) (6) System	15 Aug 2020 13:33:13

US3042203

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'Jan 2018'	(b) (4), (b) (6) System	15 Aug 2020 13:33:13

US3042203

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2018'	(b) (4), (b) (6) System	15 Aug 2020 13:33:13

US3042203

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:57:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 22:17:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 22:17:10
	(b) (4)	
Data point term sent to Coder	System	13 Jan 2021 22:16:46
User entered 'DEPRESSION'	Rylea Gulick (b) (4)	13 Jan 2021 22:15:59
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'UN May 2020'	Rylea Gulick (b) (4)	13 Jan 2021 22:15:59
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:15:59

US3042203

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:57:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:15:59

US3042203

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	13 Jan 2021 22:15:59
	(b) (4)	

US3042203

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:57:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:15:59

US3042203

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'May 2020'	(b) (4), (b) (6) System	13 Jan 2021 22:15:59

US3042203

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '2020'	(b) (4), (b) (6) System	13 Jan 2021 22:15:59

US3042203

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered empty.	(b) (4), (b) (6) System	13 Jan 2021 22:15:59

US3042203

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered empty.	(b) (4), (b) (6) System	13 Jan 2021 22:15:59

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:33:43

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:33:43

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered '13:20'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:33:43

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered '14 Aug 2020 13:20'	(b) (4), (b) (6) System	15 Aug 2020 13:33:43

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '177.8' cm	Rylea Gulick (b) (4)	15 Aug 2020 13:33:43
	(b) (4)	
DataPoint set to visible.	System	14 Aug 2020 19:35:14

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '90' kg	Rylea Gulick (b) (4)	15 Aug 2020 13:33:43
	(b) (4)	
DataPoint set to visible.	System	14 Aug 2020 19:35:14

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
Amendment Manager: User entered '28.46944'	(b) (4), (b) (6)	
User entered '28.5'	System	16 Sep 2020 23:57:54
DataPoint set to visible.	System	15 Aug 2020 13:33:43
	System	14 Aug 2020 19:35:14

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	15 Aug 2020 13:33:43
DataPoint set to visible.	System	14 Aug 2020 19:35:14

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User closed query 'Per CDM Requery : Kindly remove the Temperature unit (C) .thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 06:39:31
Query 'Per CDM Requery : Kindly remove the Temperature unit (C) .thanks ' answered with 'entry updated' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 15:51:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Oct 2020 15:51:35
User opened query 'Per CDM Requery : Kindly remove the Temperature unit (C) .thanks ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 06:58:45
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)	12 Oct 2020 06:58:45
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 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:23:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:23:49

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
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). User entered '37.1' C	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	08 Oct 2020 08:13:36 15 Aug 2020 13:33:43

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:23:49
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	15 Aug 2020 13:33:43
	(b) (4)	

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:33:43
	(b) (4)	

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	08 Oct 2020 14:23:49
change Data Entry Error		
User entered '79'	Rylea Gulick (b) (4)	15 Aug 2020 13:33:43
	(b) (4)	

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'bpm'	(b) (4), (b) (6) System	15 Aug 2020 13:33:43

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	08 Oct 2020 14:23:49
change Data Entry Error		
User entered '16'	Rylea Gulick (b) (4)	15 Aug 2020 13:33:43
	(b) (4)	

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Aug 2020 13:33:43

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:23:49
User entered '129'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:33:43

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 13:33:43

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	08 Oct 2020 14:23:49
change Data Entry Error		
User entered '79'	Rylea Gulick (b) (4)	15 Aug 2020 13:33:43
	(b) (4)	

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 13:33:43

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:07:03

US3042203

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 05:07:03

US3042203

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:33:47

US3042203

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 02:28:14
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 22:48:56
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	15 Aug 2020 13:33:47
	(b) (4)	

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

[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 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:34:19
	(b) (4)	

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

[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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

[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 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:34:19
	(b) (4)	

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:34:19
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'GOES TO GAS STATIONS WITHOUT MASK'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:34:19
	(b) (4)	

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:34:19
	(b) (4)	

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

[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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

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 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '0'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered 'I'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:19

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	15 Aug 2020 13:34:19
	(b) (4)	

US3042203

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:57:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:07:03
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:34:19
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:26

US3042203

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:26

US3042203

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[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 11:52:48
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	15 Aug 2020 13:34:26
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'VISIT1'	(b) (4), (b) (6) System	15 Aug 2020 13:34:26

US3042203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '14 AUG 2020'	RWS_ENDPOINT	14 Aug 2020 19:14:41
	ENDPOINT (b) (4)	
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:51

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:40:18
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:40:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 19:14:41
User entered '143913' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 19:14:41

US3042203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 19:14:41

US3042203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:51

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 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:32

US3042203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:51

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 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:32

US3042203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:34:32

US3042203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4)	15 Aug 2020 13:34:32
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:51

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:34:32
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:57:51

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:23:18
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'ENTRY UPDATED ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:39:03
User entered 'No (N)'	Rylea Gulick (b) (4)	29 Oct 2020 17:39:28
	(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 14:26:26
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:27
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:23:23

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
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 05:52:24
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.'	Rylea Gulick (b) (4)	28 Oct 2020 19:40:07
answered with 'ENTRY UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:39:59
	(b) (4)	
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 03:48:45
User entered '177.8' cm	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:39:59
change Data Entry Error	(b) (4)	
User entered '90' kg	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:23:18
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) (4), (b) (6)	29 Oct 2020 05:52:24
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.'	Rylea Gulick (b) (4)	28 Oct 2020 19:40:07
answered with 'ENTRY UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:39:59
	(b) (4)	
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 03:48:45
User entered '177.8' cm	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:39:59
change Data Entry Error	(b) (4)	
User entered '90' kg	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:35:23

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:35:23

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '13:20'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered '14 Aug 2020 13:20'	(b) (4), (b) (6) System	15 Aug 2020 13:35:23

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '37.1' C	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '79'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'bpm'	(b) (4), (b) (6) System	15 Aug 2020 13:35:23

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '16'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Aug 2020 13:35:23

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '129'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 13:35:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '79'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 13:35:23

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:23:18
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) (4), (b) (6)	29 Oct 2020 05:52:24
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.'	Rylea Gulick (b) (4)	28 Oct 2020 19:40:07
answered with 'ENTRY UPDATED' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Rylea Gulick (b) (4)	28 Oct 2020 19:39:59
	(b) (4)	
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 03:48:45
User entered '177.8' cm	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered missing code ND - Not Done; reason for	Rylea Gulick (b) (4)	28 Oct 2020 19:39:59
change Data Entry Error	(b) (4)	
User entered '90' kg	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:35:23

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:35:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:23:18
User closed 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).	(b) (4)	
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).	(b) (4), (b) (6)	17 Aug 2020 07:35:39
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)	15 Aug 2020 13:35:43
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).	(b) (4)	
User entered '15:09'		15 Aug 2020 13:35:23
	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered '14 Aug 2020 15:09'	(b) (4), (b) (6) System	15 Aug 2020 13:35:23

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '37.3' C	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '65'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'bpm'	(b) (4), (b) (6) System	15 Aug 2020 13:35:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '14'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Aug 2020 13:35:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '130'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 13:35:23

US3042203

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '70'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'mmHg'	(b) (4), (b) (6) System	15 Aug 2020 13:35:23

US3042203

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	15 Aug 2020 13:35:50
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	14 Aug 2020 19:35:28
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	14 Aug 2020 19:35:28
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 19:35:28

US3042203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	14 Aug 2020 19:35:28

US3042203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:23:18
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 19:35:28

US3042203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '14:32'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 19:35:28

US3042203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered '14 Aug 2020 14:32'	(b) (4), (b) (6) System	14 Aug 2020 19:35:28

US3042203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	14 Aug 2020 19:35:28

US3042203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'ONCE'	(b) (4), (b) (6) System	14 Aug 2020 19:35:28

US3042203

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	14 Aug 2020 19:35:28

US3042203

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:36:08
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '14 Aug 2020'	Rylea Gulick (b) (4)	15 Aug 2020 13:36:08
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '14:08'	Rylea Gulick (b) (4)	15 Aug 2020 13:36:08
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered '14 Aug 2020 14:08'	(b) (4), (b) (6) System	15 Aug 2020 13:36:08

US3042203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:57:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '14 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:36:27

US3042203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:36:27

US3042203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:36:27

US3042203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '14:01'	Rylea Gulick (b) (4)	15 Aug 2020 13:36:27
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered '14 Aug 2020 14:01'	(b) (4), (b) (6) System	15 Aug 2020 13:36:27

US3042203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:36:27

US3042203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:36:27

US3042203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:36:27

US3042203

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered empty.	(b) (4), (b) (6) System	15 Aug 2020 13:36:27

US3042203

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:36:29
	(b) (4)	

US3042203

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:52:48
User entered 'I'	(b) (4), (b) (6) System	15 Aug 2020 13:36:29

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:03:38', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'cc975a97-864a-40c1-90a3-27d3f1f48285'	System	14 Aug 2020 20:04:18
User entered 'Yes (Y)'	System	14 Aug 2020 20:04:18

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:03:47', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'cc975a97-864a-40c1-90a3-27d3f1f48285'	System	14 Aug 2020 20:04:18
User entered '99.3'	System	14 Aug 2020 20:04:18

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:04:11', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'cc975a97-864a-40c1-90a3-27d3f1f48285'	System	14 Aug 2020 20:04:18
User entered 'No (N)'	System	14 Aug 2020 20:04:18

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:04:16', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'cc975a97-864a-40c1-90a3-27d3f1f48285'	System	14 Aug 2020 20:04:18
User entered '14 Aug 2020 15:04'	System	14 Aug 2020 20:04:18

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Aug 2020 14:52'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Aug 2020 17:22'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:53:33', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '97e3b63c-8295-4501-bc2e-54aa2586e507'	System	14 Aug 2020 23:53:57
User entered 'Yes (Y)'	System	14 Aug 2020 23:53:57

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:53:47', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '97e3b63c-8295-4501-bc2e-54aa2586e507'	System	14 Aug 2020 23:53:57
User entered '98.8'	System	14 Aug 2020 23:53:57

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:53:53', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '97e3b63c-8295-4501-bc2e-54aa2586e507'	System	14 Aug 2020 23:53:57
User entered 'No (N)'	System	14 Aug 2020 23:53:57

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:53:57', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '97e3b63c-8295-4501-bc2e-54aa2586e507'	System	14 Aug 2020 23:53:57
User entered '14 Aug 2020 18:53'	System	14 Aug 2020 23:53:57

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Aug 2020 18:17'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 2'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:03:41', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'daccf639-2644-462d-8356-8a206fdafd67'	System	15 Aug 2020 17:04:07
User entered 'Yes (Y)'	System	15 Aug 2020 17:04:07

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:03:51', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'daccf639-2644-462d-8356-8a206fd6cd67'	System	15 Aug 2020 17:04:07
User entered '97.6'	System	15 Aug 2020 17:04:07

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:03:56', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'daccf639-2644-462d-8356-8a206fdafd67'	System	15 Aug 2020 17:04:07
User entered 'No (N)'	System	15 Aug 2020 17:04:07

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:04:02', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'daccf639-2644-462d-8356-8a206fdafd67'	System	15 Aug 2020 17:04:07
User entered '15 Aug 2020 12:04'	System	15 Aug 2020 17:04:07

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 3'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:53:11', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '4435b5ff-8f07-4fff-ac34-cb523297d073'	System	16 Aug 2020 21:53:35
User entered 'Yes (Y)'	System	16 Aug 2020 21:53:35

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:53:19', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '4435b5ff-8f07-4fff-ac34-cb523297d073'	System	16 Aug 2020 21:53:35
User entered '98.2'	System	16 Aug 2020 21:53:35

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:53:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '4435b5ff-8f07-4fff-ac34-cb523297d073'	System	16 Aug 2020 21:53:35
User entered 'No (N)'	System	16 Aug 2020 21:53:35

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:53:30', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '4435b5ff-8f07-4fff-ac34-cb523297d073'	System	16 Aug 2020 21:53:35
User entered '16 Aug 2020 16:53'	System	16 Aug 2020 21:53:35

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 4'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:01', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9e5828b9-1795-493a-8b7d-65de05309cbb'	System	17 Aug 2020 21:25:23
User entered 'Yes (Y)'	System	17 Aug 2020 21:25:23

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:07', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9e5828b9-1795-493a-8b7d-65de05309cbb'	System	17 Aug 2020 21:25:23
User entered '98.8'	System	17 Aug 2020 21:25:23

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:11', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9e5828b9-1795-493a-8b7d-65de05309cbb'	System	17 Aug 2020 21:25:23
User entered 'No (N)'	System	17 Aug 2020 21:25:23

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:22', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9e5828b9-1795-493a-8b7d-65de05309cbb'	System	17 Aug 2020 21:25:23
User entered '17 Aug 2020 16:25'	System	17 Aug 2020 21:25:23

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 5'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:19:22', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'bdbbeab77-e4b6-454d-912a-2131d1f0171a'	System	18 Aug 2020 21:19:39
User entered 'Yes (Y)'	System	18 Aug 2020 21:19:39

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:19:28', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'bdbbeab77-e4b6-454d-912a-2131d1f0171a'	System	18 Aug 2020 21:19:39
User entered '97.8'	System	18 Aug 2020 21:19:39

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:19:33', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'bdbbeab77-e4b6-454d-912a-2131d1f0171a'	System	18 Aug 2020 21:19:39
User entered 'No (N)'	System	18 Aug 2020 21:19:39

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:19:37', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'bdbaab77-e4b6-454d-912a-2131d1f0171a'	System	18 Aug 2020 21:19:39
User entered '18 Aug 2020 16:19'	System	18 Aug 2020 21:19:39

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 6'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:41:16', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5b7c8551-d267-4f9e-b14a-1598242aea57'	System	19 Aug 2020 20:41:28
User entered 'Yes (Y)'	System	19 Aug 2020 20:41:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:41:21', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5b7c8551-d267-4f9e-b14a-1598242aea57'	System	19 Aug 2020 20:41:28
User entered '99.1'	System	19 Aug 2020 20:41:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:41:24', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5b7c8551-d267-4f9e-b14a-1598242aea57'	System	19 Aug 2020 20:41:28
User entered 'No (N)'	System	19 Aug 2020 20:41:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:41:27', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5b7c8551-d267-4f9e-b14a-1598242aea57'	System	19 Aug 2020 20:41:28
User entered '19 Aug 2020 15:41'	System	19 Aug 2020 20:41:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 7'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:36:33', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e79d7283-95f0-4b9d-86eb-356b8f073cd3'	System	21 Aug 2020 00:36:48
User entered 'Yes (Y)'	System	21 Aug 2020 00:36:48

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:36:40', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e79d7283-95f0-4b9d-86eb-356b8f073cd3'	System	21 Aug 2020 00:36:48
User entered '98.1'	System	21 Aug 2020 00:36:48

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:36:43', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e79d7283-95f0-4b9d-86eb-356b8f073cd3'	System	21 Aug 2020 00:36:48
User entered 'No (N)'	System	21 Aug 2020 00:36:48

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:36:47', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e79d7283-95f0-4b9d-86eb-356b8f073cd3'	System	21 Aug 2020 00:36:48
User entered '20 Aug 2020 19:36'	System	21 Aug 2020 00:36:48

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:19
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:02:23', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '0dbd7480-d18d-47e7-981c-6ad0169b27eb'	System	14 Aug 2020 20:02:45
User entered 'None (1)'	System	14 Aug 2020 20:02:45

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:02:31', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '0dbd7480-d18d-47e7-981c-6ad0169b27eb'	System	14 Aug 2020 20:02:45
User entered 'No (N)'	System	14 Aug 2020 20:02:45

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:02:34', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '0dbd7480-d18d-47e7-981c-6ad0169b27eb'	System	14 Aug 2020 20:02:45
User entered 'No (N)'	System	14 Aug 2020 20:02:45

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:02:39', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '0dbd7480-d18d-47e7-981c-6ad0169b27eb'	System	14 Aug 2020 20:02:45
User entered 'None (1)'	System	14 Aug 2020 20:02:45

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:02:45', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '0dbd7480-d18d-47e7-981c-6ad0169b27eb'	System	14 Aug 2020 20:02:45
User entered '14 Aug 2020 15:02'	System	14 Aug 2020 20:02:45

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Aug 2020 14:52'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Aug 2020 17:22'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:05', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '4364ece7-53d9-425d-8c5b-415e1b25dd0b'	System	14 Aug 2020 23:54:20
User entered 'None (1)'	System	14 Aug 2020 23:54:20

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:08', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '4364ece7-53d9-425d-8c5b-415e1b25dd0b'	System	14 Aug 2020 23:54:20
User entered 'No (N)'	System	14 Aug 2020 23:54:20

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:11', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '4364ece7-53d9-425d-8c5b-415e1b25dd0b'	System	14 Aug 2020 23:54:20
User entered 'No (N)'	System	14 Aug 2020 23:54:20

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:17', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '4364ece7-53d9-425d-8c5b-415e1b25dd0b'	System	14 Aug 2020 23:54:20
User entered 'None (1)'	System	14 Aug 2020 23:54:20

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:20', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '4364ece7-53d9-425d-8c5b-415e1b25dd0b'	System	14 Aug 2020 23:54:20
User entered '14 Aug 2020 18:54'	System	14 Aug 2020 23:54:20

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Aug 2020 18:17'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 2'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:04:15', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2ef6f9ce-e2b6-4361-a81d-dad95fda6b0c'	System	15 Aug 2020 17:04:47
User entered 'None (1)'	System	15 Aug 2020 17:04:47

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:04:19', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2ef6f9ce-e2b6-4361-a81d-dad95fda6b0c'	System	15 Aug 2020 17:04:47
User entered 'No (N)'	System	15 Aug 2020 17:04:47

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:04:32', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2ef6f9ce-e2b6-4361-a81d-dad95fda6b0c'	System	15 Aug 2020 17:04:47
User entered 'No (N)'	System	15 Aug 2020 17:04:47

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:04:41', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2ef6f9ce-e2b6-4361-a81d-dad95fda6b0c'	System	15 Aug 2020 17:04:47
User entered 'None (1)'	System	15 Aug 2020 17:04:47

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:04:47', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2ef6f9ce-e2b6-4361-a81d-dad95fda6b0c'	System	15 Aug 2020 17:04:47
User entered '15 Aug 2020 12:04'	System	15 Aug 2020 17:04:47

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 3'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:53:37', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '124b85ed-1189-4a8e-ba9c-eb7b6183585d'	System	16 Aug 2020 21:53:55
User entered 'None (1)'	System	16 Aug 2020 21:53:55

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:53:39', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '124b85ed-1189-4a8e-ba9c-eb7b6183585d'	System	16 Aug 2020 21:53:55
User entered 'No (N)'	System	16 Aug 2020 21:53:55

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:53:42', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '124b85ed-1189-4a8e-ba9c-eb7b6183585d'	System	16 Aug 2020 21:53:55
User entered 'No (N)'	System	16 Aug 2020 21:53:55

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:53:51', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '124b85ed-1189-4a8e-ba9c-eb7b6183585d'	System	16 Aug 2020 21:53:55
User entered 'None (1)'	System	16 Aug 2020 21:53:55

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:53:54', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '124b85ed-1189-4a8e-ba9c-eb7b6183585d'	System	16 Aug 2020 21:53:55
User entered '16 Aug 2020 16:53'	System	16 Aug 2020 21:53:55

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 4'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:28', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2ca40446-92f2-43ae-a13b-c3d8521f92f7'	System	17 Aug 2020 21:25:44
User entered 'None (1)'	System	17 Aug 2020 21:25:44

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:31', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2ca40446-92f2-43ae-a13b-c3d8521f92f7'	System	17 Aug 2020 21:25:44
User entered 'No (N)'	System	17 Aug 2020 21:25:44

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:35', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2ca40446-92f2-43ae-a13b-c3d8521f92f7'	System	17 Aug 2020 21:25:44
User entered 'No (N)'	System	17 Aug 2020 21:25:44

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:39', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2ca40446-92f2-43ae-a13b-c3d8521f92f7'	System	17 Aug 2020 21:25:44
User entered 'None (1)'	System	17 Aug 2020 21:25:44

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:43', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2ca40446-92f2-43ae-a13b-c3d8521f92f7'	System	17 Aug 2020 21:25:44
User entered '17 Aug 2020 16:25'	System	17 Aug 2020 21:25:44

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 5'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:19:43', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '29cf8a63-b524-44a5-a13e-f3b0f1c38477'	System	18 Aug 2020 21:19:59
User entered 'None (1)'	System	18 Aug 2020 21:19:59

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:19:45', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '29cf8a63-b524-44a5-a13e-f3b0f1c38477'	System	18 Aug 2020 21:19:59
User entered 'No (N)'	System	18 Aug 2020 21:19:59

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:19:48', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '29cf8a63-b524-44a5-a13e-f3b0f1c38477'	System	18 Aug 2020 21:19:59
User entered 'No (N)'	System	18 Aug 2020 21:19:59

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:19:53', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '29cf8a63-b524-44a5-a13e-f3b0f1c38477'	System	18 Aug 2020 21:19:59
User entered 'None (1)'	System	18 Aug 2020 21:19:59

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:19:57', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '29cf8a63-b524-44a5-a13e-f3b0f1c38477'	System	18 Aug 2020 21:19:59
User entered '18 Aug 2020 16:19'	System	18 Aug 2020 21:19:59

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 6'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:41:42', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'dd43e2ee-1b38-4064-95f6-fe2719bb146e'	System	19 Aug 2020 20:42:08
User entered 'None (1)'	System	19 Aug 2020 20:42:08

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:41:44', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'dd43e2ee-1b38-4064-95f6-fe2719bb146e'	System	19 Aug 2020 20:42:08
User entered 'No (N)'	System	19 Aug 2020 20:42:08

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:41:49', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'dd43e2ee-1b38-4064-95f6-fe2719bb146e'	System	19 Aug 2020 20:42:08
User entered 'No (N)'	System	19 Aug 2020 20:42:08

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:41:52', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'dd43e2ee-1b38-4064-95f6-fe2719bb146e'	System	19 Aug 2020 20:42:08
User entered 'None (1)'	System	19 Aug 2020 20:42:08

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:41:55', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'dd43e2ee-1b38-4064-95f6-fe2719bb146e'	System	19 Aug 2020 20:42:08
User entered '19 Aug 2020 15:41'	System	19 Aug 2020 20:42:08

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 7'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:36:51', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '649674aa-e195-440a-9506-d3cfc0dc0b4b'	System	21 Aug 2020 00:37:03
User entered 'None (1)'	System	21 Aug 2020 00:37:03

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:36:54', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '649674aa-e195-440a-9506-d3cfc0dc0b4b'	System	21 Aug 2020 00:37:03
User entered 'No (N)'	System	21 Aug 2020 00:37:03

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:36:56', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '649674aa-e195-440a-9506-d3cfc0dc0b4b'	System	21 Aug 2020 00:37:03
User entered 'No (N)'	System	21 Aug 2020 00:37:03

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:36:59', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '649674aa-e195-440a-9506-d3cfc0dc0b4b'	System	21 Aug 2020 00:37:03
User entered 'None (1)'	System	21 Aug 2020 00:37:03

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:37:02', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '649674aa-e195-440a-9506-d3cfc0dc0b4b'	System	21 Aug 2020 00:37:03
User entered '20 Aug 2020 19:37'	System	21 Aug 2020 00:37:03

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:27
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:04:23', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'fe9eb9c0-fb21-4058-85d9-39b6a8da2a9f'	System	14 Aug 2020 20:04:43
User entered 'None (0)'	System	14 Aug 2020 20:04:43

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:04:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'fe9eb9c0-fb21-4058-85d9-39b6a8da2a9f'	System	14 Aug 2020 20:04:43
User entered 'None (0)'	System	14 Aug 2020 20:04:43

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:04:28', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'fe9eb9c0-fb21-4058-85d9-39b6a8da2a9f'	System	14 Aug 2020 20:04:43
User entered 'None (0)'	System	14 Aug 2020 20:04:43

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:04:31', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'fe9eb9c0-fb21-4058-85d9-39b6a8da2a9f'	System	14 Aug 2020 20:04:43
User entered 'None (0)'	System	14 Aug 2020 20:04:43

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:04:35', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'fe9eb9c0-fb21-4058-85d9-39b6a8da2a9f'	System	14 Aug 2020 20:04:43
User entered 'None (0)'	System	14 Aug 2020 20:04:43

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:04:37', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'fe9eb9c0-fb21-4058-85d9-39b6a8da2a9f'	System	14 Aug 2020 20:04:43
User entered 'None (0)'	System	14 Aug 2020 20:04:43

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:04:40', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'fe9eb9c0-fb21-4058-85d9-39b6a8da2a9f'	System	14 Aug 2020 20:04:43
User entered 'No (N)'	System	14 Aug 2020 20:04:43

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T15:04:44', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'fe9eb9c0-fb21-4058-85d9-39b6a8da2a9f'	System	14 Aug 2020 20:04:43
User entered '14 Aug 2020 15:04'	System	14 Aug 2020 20:04:43

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Aug 2020 14:52'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Aug 2020 17:22'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '452c2966-dd69-42d1-be6c-be66252ab1b5'	System	14 Aug 2020 23:54:48
User entered 'None (0)'	System	14 Aug 2020 23:54:48

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:29', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '452c2966-dd69-42d1-be6c-be66252ab1b5'	System	14 Aug 2020 23:54:48
User entered 'None (0)'	System	14 Aug 2020 23:54:48

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:32', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '452c2966-dd69-42d1-be6c-be66252ab1b5'	System	14 Aug 2020 23:54:48
User entered 'None (0)'	System	14 Aug 2020 23:54:48

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:34', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '452c2966-dd69-42d1-be6c-be66252ab1b5'	System	14 Aug 2020 23:54:48
User entered 'None (0)'	System	14 Aug 2020 23:54:48

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:37', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '452c2966-dd69-42d1-be6c-be66252ab1b5'	System	14 Aug 2020 23:54:48
User entered 'None (0)'	System	14 Aug 2020 23:54:48

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:40', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '452c2966-dd69-42d1-be6c-be66252ab1b5'	System	14 Aug 2020 23:54:48
User entered 'None (0)'	System	14 Aug 2020 23:54:48

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:45', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '452c2966-dd69-42d1-be6c-be66252ab1b5'	System	14 Aug 2020 23:54:48
User entered 'No (N)'	System	14 Aug 2020 23:54:48

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-14T18:54:48', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '452c2966-dd69-42d1-be6c-be66252ab1b5'	System	14 Aug 2020 23:54:48
User entered '14 Aug 2020 18:54'	System	14 Aug 2020 23:54:48

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Aug 2020 18:17'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 2'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:04:54', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '51a76ccd-e3da-4020-ba93-87b044b63e92'	System	15 Aug 2020 17:06:15
User entered 'None (0)'	System	15 Aug 2020 17:06:15

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:05:01', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '51a76ccd-e3da-4020-ba93-87b044b63e92'	System	15 Aug 2020 17:06:15
User entered 'None (0)'	System	15 Aug 2020 17:06:15

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:05:04', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '51a76ccd-e3da-4020-ba93-87b044b63e92'	System	15 Aug 2020 17:06:15
User entered 'None (0)'	System	15 Aug 2020 17:06:15

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:05:09', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '51a76ccd-e3da-4020-ba93-87b044b63e92'	System	15 Aug 2020 17:06:15
User entered 'None (0)'	System	15 Aug 2020 17:06:15

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:05:12', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '51a76ccd-e3da-4020-ba93-87b044b63e92'	System	15 Aug 2020 17:06:15
User entered 'None (0)'	System	15 Aug 2020 17:06:15

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:05:15', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '51a76ccd-e3da-4020-ba93-87b044b63e92'	System	15 Aug 2020 17:06:15
User entered 'None (0)'	System	15 Aug 2020 17:06:15

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:05:35', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '51a76ccd-e3da-4020-ba93-87b044b63e92'	System	15 Aug 2020 17:06:15
User entered 'No (N)'	System	15 Aug 2020 17:06:15

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-15T12:06:16', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '51a76ccd-e3da-4020-ba93-87b044b63e92'	System	15 Aug 2020 17:06:15
User entered '15 Aug 2020 12:06'	System	15 Aug 2020 17:06:15

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 3'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:54:04', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '55d1bf64-c2fd-4a64-a0dc-df985c78ac06'	System	16 Aug 2020 21:54:49
User entered 'None (0)'	System	16 Aug 2020 21:54:49

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:54:08', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '55d1bf64-c2fd-4a64-a0dc-df985c78ac06'	System	16 Aug 2020 21:54:49
User entered 'None (0)'	System	16 Aug 2020 21:54:49

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:54:11', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '55d1bf64-c2fd-4a64-a0dc-df985c78ac06'	System	16 Aug 2020 21:54:49
User entered 'None (0)'	System	16 Aug 2020 21:54:49

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:54:33', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '55d1bf64-c2fd-4a64-a0dc-df985c78ac06'	System	16 Aug 2020 21:54:49
User entered 'None (0)'	System	16 Aug 2020 21:54:49

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:54:38', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '55d1bf64-c2fd-4a64-a0dc-df985c78ac06'	System	16 Aug 2020 21:54:49
User entered 'None (0)'	System	16 Aug 2020 21:54:49

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:54:40', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '55d1bf64-c2fd-4a64-a0dc-df985c78ac06'	System	16 Aug 2020 21:54:49
User entered 'None (0)'	System	16 Aug 2020 21:54:49

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:54:44', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '55d1bf64-c2fd-4a64-a0dc-df985c78ac06'	System	16 Aug 2020 21:54:49
User entered 'No (N)'	System	16 Aug 2020 21:54:49

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-16T16:54:47', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '55d1bf64-c2fd-4a64-a0dc-df985c78ac06'	System	16 Aug 2020 21:54:49
User entered '16 Aug 2020 16:54'	System	16 Aug 2020 21:54:49

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 4'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:49', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '778b32b1-3404-40af-abcb-264c0c9ba731'	System	17 Aug 2020 21:26:13
User entered 'None (0)'	System	17 Aug 2020 21:26:13

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:51', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '778b32b1-3404-40af-abcb-264c0c9ba731'	System	17 Aug 2020 21:26:13
User entered 'None (0)'	System	17 Aug 2020 21:26:13

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:53', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '778b32b1-3404-40af-abcb-264c0c9ba731'	System	17 Aug 2020 21:26:13
User entered 'None (0)'	System	17 Aug 2020 21:26:13

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:25:57', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '778b32b1-3404-40af-abcb-264c0c9ba731'	System	17 Aug 2020 21:26:13
User entered 'None (0)'	System	17 Aug 2020 21:26:13

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:26:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '778b32b1-3404-40af-abcb-264c0c9ba731'	System	17 Aug 2020 21:26:13
User entered 'None (0)'	System	17 Aug 2020 21:26:13

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:26:02', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '778b32b1-3404-40af-abcb-264c0c9ba731'	System	17 Aug 2020 21:26:13
User entered 'None (0)'	System	17 Aug 2020 21:26:13

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:26:05', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '778b32b1-3404-40af-abcb-264c0c9ba731'	System	17 Aug 2020 21:26:13
User entered 'No (N)'	System	17 Aug 2020 21:26:13

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-17T16:26:08', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '778b32b1-3404-40af-abcb-264c0c9ba731'	System	17 Aug 2020 21:26:13
User entered '17 Aug 2020 16:26'	System	17 Aug 2020 21:26:13

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 5'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:20:02', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '3c144432-322c-49a0-b8e3-85a0e31b5ef2'	System	18 Aug 2020 21:20:26
User entered 'None (0)'	System	18 Aug 2020 21:20:26

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:20:05', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '3c144432-322c-49a0-b8e3-85a0e31b5ef2'	System	18 Aug 2020 21:20:26
User entered 'None (0)'	System	18 Aug 2020 21:20:26

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:20:07', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '3c144432-322c-49a0-b8e3-85a0e31b5ef2'	System	18 Aug 2020 21:20:26
User entered 'None (0)'	System	18 Aug 2020 21:20:26

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:20:10', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '3c144432-322c-49a0-b8e3-85a0e31b5ef2'	System	18 Aug 2020 21:20:26
User entered 'None (0)'	System	18 Aug 2020 21:20:26

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:20:12', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '3c144432-322c-49a0-b8e3-85a0e31b5ef2'	System	18 Aug 2020 21:20:26
User entered 'None (0)'	System	18 Aug 2020 21:20:26

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:20:14', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '3c144432-322c-49a0-b8e3-85a0e31b5ef2'	System	18 Aug 2020 21:20:26
User entered 'None (0)'	System	18 Aug 2020 21:20:26

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:20:18', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '3c144432-322c-49a0-b8e3-85a0e31b5ef2'	System	18 Aug 2020 21:20:26
User entered 'No (N)'	System	18 Aug 2020 21:20:26

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-18T16:20:21', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '3c144432-322c-49a0-b8e3-85a0e31b5ef2'	System	18 Aug 2020 21:20:26
User entered '18 Aug 2020 16:20'	System	18 Aug 2020 21:20:26

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 6'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:42:01', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e5229754-9394-4ca1-a340-e9cd24a596c3'	System	19 Aug 2020 20:42:27
User entered 'None (0)'	System	19 Aug 2020 20:42:27

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:42:03', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e5229754-9394-4ca1-a340-e9cd24a596c3'	System	19 Aug 2020 20:42:27
User entered 'None (0)'	System	19 Aug 2020 20:42:27

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:42:05', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e5229754-9394-4ca1-a340-e9cd24a596c3'	System	19 Aug 2020 20:42:27
User entered 'None (0)'	System	19 Aug 2020 20:42:27

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:42:08', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e5229754-9394-4ca1-a340-e9cd24a596c3'	System	19 Aug 2020 20:42:27
User entered 'None (0)'	System	19 Aug 2020 20:42:27

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:42:10', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e5229754-9394-4ca1-a340-e9cd24a596c3'	System	19 Aug 2020 20:42:27
User entered 'None (0)'	System	19 Aug 2020 20:42:27

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:42:13', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e5229754-9394-4ca1-a340-e9cd24a596c3'	System	19 Aug 2020 20:42:27
User entered 'None (0)'	System	19 Aug 2020 20:42:27

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:42:23', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e5229754-9394-4ca1-a340-e9cd24a596c3'	System	19 Aug 2020 20:42:27
User entered 'No (N)'	System	19 Aug 2020 20:42:27

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-19T15:42:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e5229754-9394-4ca1-a340-e9cd24a596c3'	System	19 Aug 2020 20:42:27
User entered '19 Aug 2020 15:42'	System	19 Aug 2020 20:42:27

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 7'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:37:07', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'bb9607d7-c5c7-4407-8c36-6f05ed173297'	System	21 Aug 2020 00:37:25
User entered 'None (0)'	System	21 Aug 2020 00:37:25

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:37:09', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'bb9607d7-c5c7-4407-8c36-6f05ed173297'	System	21 Aug 2020 00:37:25
User entered 'None (0)'	System	21 Aug 2020 00:37:25

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:37:11', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'bb9607d7-c5c7-4407-8c36-6f05ed173297'	System	21 Aug 2020 00:37:25
User entered 'None (0)'	System	21 Aug 2020 00:37:25

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:37:12', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'bb9607d7-c5c7-4407-8c36-6f05ed173297'	System	21 Aug 2020 00:37:25
User entered 'None (0)'	System	21 Aug 2020 00:37:25

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:37:14', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'bb9607d7-c5c7-4407-8c36-6f05ed173297'	System	21 Aug 2020 00:37:25
User entered 'None (0)'	System	21 Aug 2020 00:37:25

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:37:16', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'bb9607d7-c5c7-4407-8c36-6f05ed173297'	System	21 Aug 2020 00:37:25
User entered 'None (0)'	System	21 Aug 2020 00:37:25

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:37:20', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'bb9607d7-c5c7-4407-8c36-6f05ed173297'	System	21 Aug 2020 00:37:25
User entered 'No (N)'	System	21 Aug 2020 00:37:25

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-08-20T19:37:23', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'bb9607d7-c5c7-4407-8c36-6f05ed173297'	System	21 Aug 2020 00:37:25
User entered '20 Aug 2020 19:37'	System	21 Aug 2020 00:37:25

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 19:35:28

US3042203

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:38
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:50:55
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	26 Aug 2020 15:30:37
	(b) (4)	

US3042203

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:50:55
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '21 Aug 2020'	Rylea Gulick (b) (4)	26 Aug 2020 15:30:37
	(b) (4)	

US3042203

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:50:55
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4)	26 Aug 2020 15:30:37

US3042203

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:50:55
User signature succeeded.	(b) (4), (b) (6)	
	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	26 Aug 2020 15:30:37
	(b) (4)	

US3042203

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:50:55
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	26 Aug 2020 15:30:38
	(b) (4)	

US3042203

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:50:55
User entered 'I'	(b) (4), (b) (6) System	26 Aug 2020 15:30:38

US3042203

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Sep 2020 13:38:25

US3042203

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '28 Aug 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Sep 2020 13:38:25

US3042203

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Sep 2020 13:38:25

US3042203

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	01 Sep 2020 13:38:25
	(b) (4)	

US3042203

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	01 Sep 2020 13:38:26

US3042203

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User entered 'I'	(b) (4), (b) (6) System	01 Sep 2020 13:38:26

US3042203

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:07
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Sep 2020 20:33:15
	(b) (4)	

US3042203

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 06:55:28
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'SUBJECT WAS LEFT A MESSAGE ON 05SEP2020 AND WAS REACHED ON 08SEP2020' (Site from System).	Rylea Gulick (b) (4) (b) (4)	11 Sep 2020 20:33:33
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Sep 2020 20:33:15
User entered '08 Sep 2020'	Rylea Gulick (b) (4) (b) (4)	11 Sep 2020 20:33:15

US3042203

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:07
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	11 Sep 2020 20:33:15

US3042203

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:07
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	11 Sep 2020 20:33:15
	(b) (4)	

US3042203

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:07
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Sep 2020 20:33:36
	(b) (4)	

US3042203

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:32:07
User entered 'I'	(b) (4), (b) (6) System	11 Sep 2020 20:33:36

US3042203

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Sep 2020 22:48:56
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '11 Sep 2020'	Rylea Gulick (b) (4)	11 Sep 2020 22:48:56
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[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 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	11 Sep 2020 22:48:56
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered 'VISIT2'	(b) (4), (b) (6) System	11 Sep 2020 22:48:56

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '11 Sep 2020'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	11 Sep 2020 22:50:27
User entered '14:51' reason for change: Data Entry Error	Rylea Gulick (b) (4)	11 Sep 2020 22:50:27
	(b) (4)	
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	11 Sep 2020 22:49:58
User entered '15:51'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User entered '11 Sep 2020 14:51'	System	11 Sep 2020 22:50:27
User entered '11 Sep 2020 15:51'	System	11 Sep 2020 22:49:58

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '36.8' C	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '74'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered 'bpm'	(b) (4), (b) (6) System	11 Sep 2020 22:49:58

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '14'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Sep 2020 22:49:58

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '130'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 22:49:58

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '77'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 22:49:58

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '11 Sep 2020'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '16:05'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered '11 Sep 2020 16:05'	(b) (4), (b) (6) System	11 Sep 2020 22:49:58

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '37.5' C	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '76'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered 'bpm'	(b) (4), (b) (6) System	11 Sep 2020 22:49:58

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '14'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Sep 2020 22:49:58

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '136'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 22:49:58

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '80'	Rylea Gulick (b) (4)	11 Sep 2020 22:49:58
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 22:49:58

US3042203

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Sep 2020 22:50:50
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '11 Sep 2020'	Rylea Gulick (b) (4)	11 Sep 2020 22:50:50
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Sep 2020 20:33:48
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	11 Sep 2020 20:33:48
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	11 Sep 2020 20:33:48
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	11 Sep 2020 20:33:48

US3042203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '11 Sep 2020'	Rylea Gulick (b) (4)	11 Sep 2020 20:33:48
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '15:31'	Rylea Gulick (b) (4)	11 Sep 2020 20:33:48
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered '11 Sep 2020 15:31'	(b) (4), (b) (6) System	11 Sep 2020 20:33:48

US3042203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4)	11 Sep 2020 20:33:48
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered 'ONCE'	(b) (4), (b) (6) System	11 Sep 2020 20:33:48

US3042203

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	11 Sep 2020 20:33:48

US3042203

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Sep 2020 22:51:02
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '11 Sep 2020'	Rylea Gulick (b) (4)	11 Sep 2020 22:51:02
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '15:13'	Rylea Gulick (b) (4)	11 Sep 2020 22:51:02
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered '11 Sep 2020 15:13'	(b) (4), (b) (6) System	11 Sep 2020 22:51:02

US3042203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:57:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '11 Sep 2020'	Rylea Gulick (b) (4)	11 Sep 2020 22:51:10
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Rylea Gulick (b) (4)	11 Sep 2020 22:51:10
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Sep 2020 22:51:10
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '15:06'	Rylea Gulick (b) (4)	11 Sep 2020 22:51:10
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered '11 Sep 2020 15:06'	(b) (4), (b) (6) System	11 Sep 2020 22:51:10

US3042203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Rylea Gulick (b) (4)	11 Sep 2020 22:51:10
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	11 Sep 2020 22:51:10
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	11 Sep 2020 22:51:10
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered empty.	(b) (4), (b) (6) System	11 Sep 2020 22:51:10

US3042203

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	11 Sep 2020 22:51:13
	(b) (4)	

US3042203

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:10:22
User entered '1'	(b) (4), (b) (6) System	11 Sep 2020 22:51:13

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:02:42', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '813f3660-3d8c-4e9c-a8f7-f87b159a0778'	System	11 Sep 2020 21:03:00
User entered 'Yes (Y)'	System	11 Sep 2020 21:03:00

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:02:49', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '813f3660-3d8c-4e9c-a8f7-f87b159a0778'	System	11 Sep 2020 21:03:00
User entered '99.5'	System	11 Sep 2020 21:03:00

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:02:53', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '813f3660-3d8c-4e9c-a8f7-f87b159a0778'	System	11 Sep 2020 21:03:00
User entered 'No (N)'	System	11 Sep 2020 21:03:00

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:02:58', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '813f3660-3d8c-4e9c-a8f7-f87b159a0778'	System	11 Sep 2020 21:03:00
User entered '11 Sep 2020 16:02'	System	11 Sep 2020 21:03:00

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '11 Sep 2020 15:51'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '11 Sep 2020 18:21'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:22:19', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9d898933-2052-4cb2-831a-9acaf80894c9'	System	12 Sep 2020 01:22:38
User entered 'Yes (Y)'	System	12 Sep 2020 01:22:38

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:22:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9d898933-2052-4cb2-831a-9acaf80894c9'	System	12 Sep 2020 01:22:38
User entered '98.9'	System	12 Sep 2020 01:22:38

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:22:29', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9d898933-2052-4cb2-831a-9acaf80894c9'	System	12 Sep 2020 01:22:38
User entered 'No (N)'	System	12 Sep 2020 01:22:38

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:22:34', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9d898933-2052-4cb2-831a-9acaf80894c9'	System	12 Sep 2020 01:22:38
User entered '11 Sep 2020 20:22'	System	12 Sep 2020 01:22:38

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '11 Sep 2020 19:16'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 2'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:57:57', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '035dac60-8fa4-483d-a6c1-ed821c978cb4'	System	13 Sep 2020 02:58:12
User entered 'Yes (Y)'	System	13 Sep 2020 02:58:12

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:03', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '035dac60-8fa4-483d-a6c1-ed821c978cb4'	System	13 Sep 2020 02:58:12
User entered '97.7'	System	13 Sep 2020 02:58:12

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:07', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '035dac60-8fa4-483d-a6c1-ed821c978cb4'	System	13 Sep 2020 02:58:12
User entered 'No (N)'	System	13 Sep 2020 02:58:12

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:11', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '035dac60-8fa4-483d-a6c1-ed821c978cb4'	System	13 Sep 2020 02:58:12
User entered '12 Sep 2020 21:58'	System	13 Sep 2020 02:58:12

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 3'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:58:47', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e35a77d0-b6e3-4b59-b9e2-9c46b5a8adb0'	System	13 Sep 2020 23:59:00
User entered 'Yes (Y)'	System	13 Sep 2020 23:59:00

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:58:52', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e35a77d0-b6e3-4b59-b9e2-9c46b5a8adb0'	System	13 Sep 2020 23:59:00
User entered '98.8'	System	13 Sep 2020 23:59:00

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:58:55', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e35a77d0-b6e3-4b59-b9e2-9c46b5a8adb0'	System	13 Sep 2020 23:59:00
User entered 'No (N)'	System	13 Sep 2020 23:59:00

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:58:58', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e35a77d0-b6e3-4b59-b9e2-9c46b5a8adb0'	System	13 Sep 2020 23:59:00
User entered '13 Sep 2020 18:58'	System	13 Sep 2020 23:59:00

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 4'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:54:17', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a3e9714a-0e52-44dc-bef4-5c65d216238a'	System	14 Sep 2020 23:54:33
User entered 'Yes (Y)'	System	14 Sep 2020 23:54:33

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:54:25', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a3e9714a-0e52-44dc-bef4-5c65d216238a'	System	14 Sep 2020 23:54:33
User entered '97.9'	System	14 Sep 2020 23:54:33

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:54:28', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a3e9714a-0e52-44dc-bef4-5c65d216238a'	System	14 Sep 2020 23:54:33
User entered 'No (N)'	System	14 Sep 2020 23:54:33

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:54:31', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a3e9714a-0e52-44dc-bef4-5c65d216238a'	System	14 Sep 2020 23:54:33
User entered '14 Sep 2020 18:54'	System	14 Sep 2020 23:54:33

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 5'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:48:45', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9b4afe64-402b-4908-9d03-239b30fe2650'	System	16 Sep 2020 00:48:58
User entered 'Yes (Y)'	System	16 Sep 2020 00:48:58

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:48:50', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9b4afe64-402b-4908-9d03-239b30fe2650'	System	16 Sep 2020 00:48:58
User entered '97.7'	System	16 Sep 2020 00:48:58

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:48:55', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9b4afe64-402b-4908-9d03-239b30fe2650'	System	16 Sep 2020 00:48:58
User entered 'No (N)'	System	16 Sep 2020 00:48:58

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:48:58', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9b4afe64-402b-4908-9d03-239b30fe2650'	System	16 Sep 2020 00:48:58
User entered '15 Sep 2020 19:48'	System	16 Sep 2020 00:48:58

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 6'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 7'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T15:58:27', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'd47eef47-4023-4771-93b3-5447acaa0cf1'	System	17 Sep 2020 20:58:47
User entered 'Yes (Y)'	System	17 Sep 2020 20:58:47

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T15:58:32', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'd47eef47-4023-4771-93b3-5447acaa0cf1'	System	17 Sep 2020 20:58:47
User entered '97.9'	System	17 Sep 2020 20:58:47

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T15:58:41', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'd47eef47-4023-4771-93b3-5447acaa0cf1'	System	17 Sep 2020 20:58:47
User entered 'No (N)'	System	17 Sep 2020 20:58:47

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T15:58:44', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'd47eef47-4023-4771-93b3-5447acaa0cf1'	System	17 Sep 2020 20:58:47
User entered '17 Sep 2020 15:58'	System	17 Sep 2020 20:58:47

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:08:57
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:03:04', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a285a381-16ad-46d3-8e1c-025da75e8b13'	System	11 Sep 2020 21:03:43
User entered 'None (1)'	System	11 Sep 2020 21:03:43

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:03:06', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a285a381-16ad-46d3-8e1c-025da75e8b13'	System	11 Sep 2020 21:03:43
User entered 'No (N)'	System	11 Sep 2020 21:03:43

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:03:29', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a285a381-16ad-46d3-8e1c-025da75e8b13'	System	11 Sep 2020 21:03:43
User entered 'No (N)'	System	11 Sep 2020 21:03:43

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:03:35', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a285a381-16ad-46d3-8e1c-025da75e8b13'	System	11 Sep 2020 21:03:43
User entered 'None (1)'	System	11 Sep 2020 21:03:43

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:03:39', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a285a381-16ad-46d3-8e1c-025da75e8b13'	System	11 Sep 2020 21:03:43
User entered '11 Sep 2020 16:03'	System	11 Sep 2020 21:03:43

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '11 Sep 2020 15:51'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '11 Sep 2020 18:21'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:22:40', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '89397cf1-65d9-49cb-a310-e64175f059ef'	System	12 Sep 2020 01:23:00
User entered 'None (1)'	System	12 Sep 2020 01:23:00

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:22:43', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '89397cf1-65d9-49cb-a310-e64175f059ef'	System	12 Sep 2020 01:23:00
User entered 'No (N)'	System	12 Sep 2020 01:23:00

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:22:47', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '89397cf1-65d9-49cb-a310-e64175f059ef'	System	12 Sep 2020 01:23:00
User entered 'No (N)'	System	12 Sep 2020 01:23:00

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:22:54', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '89397cf1-65d9-49cb-a310-e64175f059ef'	System	12 Sep 2020 01:23:00
User entered 'None (1)'	System	12 Sep 2020 01:23:00

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:22:58', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '89397cf1-65d9-49cb-a310-e64175f059ef'	System	12 Sep 2020 01:23:00
User entered '11 Sep 2020 20:22'	System	12 Sep 2020 01:23:00

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '11 Sep 2020 19:16'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 2'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:18', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '7ea7c26c-b8d8-47d2-859f-e908b666f0e7'	System	13 Sep 2020 02:58:39
User entered 'None (1)'	System	13 Sep 2020 02:58:39

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:21', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '7ea7c26c-b8d8-47d2-859f-e908b666f0e7'	System	13 Sep 2020 02:58:39
User entered 'No (N)'	System	13 Sep 2020 02:58:39

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:29', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '7ea7c26c-b8d8-47d2-859f-e908b666f0e7'	System	13 Sep 2020 02:58:39
User entered 'No (N)'	System	13 Sep 2020 02:58:39

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:33', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '7ea7c26c-b8d8-47d2-859f-e908b666f0e7'	System	13 Sep 2020 02:58:39
User entered 'None (1)'	System	13 Sep 2020 02:58:39

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:35', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '7ea7c26c-b8d8-47d2-859f-e908b666f0e7'	System	13 Sep 2020 02:58:39
User entered '12 Sep 2020 21:58'	System	13 Sep 2020 02:58:39

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 3'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:03', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5bfbf712-b63f-4721-8af7-2f6983786aad'	System	13 Sep 2020 23:59:41
User entered 'None (1)'	System	13 Sep 2020 23:59:41

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:06', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5bfbf712-b63f-4721-8af7-2f6983786aad'	System	13 Sep 2020 23:59:41
User entered 'No (N)'	System	13 Sep 2020 23:59:41

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:09', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5bfbf712-b63f-4721-8af7-2f6983786aad'	System	13 Sep 2020 23:59:41
User entered 'No (N)'	System	13 Sep 2020 23:59:41

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:11', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5bfbf712-b63f-4721-8af7-2f6983786aad'	System	13 Sep 2020 23:59:41
User entered 'None (1)'	System	13 Sep 2020 23:59:41

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:16', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5bfbf712-b63f-4721-8af7-2f6983786aad'	System	13 Sep 2020 23:59:41
User entered '13 Sep 2020 18:59'	System	13 Sep 2020 23:59:41

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 4'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:54:39', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '844f3d4b-570e-49d8-aecd-06c59646c79e'	System	14 Sep 2020 23:55:06
User entered 'None (1)'	System	14 Sep 2020 23:55:06

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:54:41', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '844f3d4b-570e-49d8-aecd-06c59646c79e'	System	14 Sep 2020 23:55:06
User entered 'No (N)'	System	14 Sep 2020 23:55:06

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:54:44', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '844f3d4b-570e-49d8-aecd-06c59646c79e'	System	14 Sep 2020 23:55:06
User entered 'No (N)'	System	14 Sep 2020 23:55:06

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:55:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '844f3d4b-570e-49d8-aecd-06c59646c79e'	System	14 Sep 2020 23:55:06
User entered 'None (1)'	System	14 Sep 2020 23:55:06

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:55:05', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '844f3d4b-570e-49d8-aecd-06c59646c79e'	System	14 Sep 2020 23:55:06
User entered '14 Sep 2020 18:55'	System	14 Sep 2020 23:55:06

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 5'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:02', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '89d5cb78-6514-4bff-a069-6eb65cf9b366'	System	16 Sep 2020 00:49:17
User entered 'None (1)'	System	16 Sep 2020 00:49:17

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:06', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '89d5cb78-6514-4bff-a069-6eb65cf9b366'	System	16 Sep 2020 00:49:17
User entered 'No (N)'	System	16 Sep 2020 00:49:17

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:08', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '89d5cb78-6514-4bff-a069-6eb65cf9b366'	System	16 Sep 2020 00:49:17
User entered 'No (N)'	System	16 Sep 2020 00:49:17

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:11', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '89d5cb78-6514-4bff-a069-6eb65cf9b366'	System	16 Sep 2020 00:49:17
User entered 'None (1)'	System	16 Sep 2020 00:49:17

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:14', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '89d5cb78-6514-4bff-a069-6eb65cf9b366'	System	16 Sep 2020 00:49:17
User entered '15 Sep 2020 19:49'	System	16 Sep 2020 00:49:17

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 6'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 7'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T15:58:51', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '530678d4-424d-41ce-8b74-b30efe6706c3'	System	17 Sep 2020 20:59:28
User entered 'None (1)'	System	17 Sep 2020 20:59:28

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T15:58:55', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '530678d4-424d-41ce-8b74-b30efe6706c3'	System	17 Sep 2020 20:59:28
User entered 'No (N)'	System	17 Sep 2020 20:59:28

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T15:59:04', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '530678d4-424d-41ce-8b74-b30efe6706c3'	System	17 Sep 2020 20:59:28
User entered 'No (N)'	System	17 Sep 2020 20:59:28

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T15:59:07', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '530678d4-424d-41ce-8b74-b30efe6706c3'	System	17 Sep 2020 20:59:28
User entered 'None (1)'	System	17 Sep 2020 20:59:28

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T15:59:25', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '530678d4-424d-41ce-8b74-b30efe6706c3'	System	17 Sep 2020 20:59:28
User entered '17 Sep 2020 15:59'	System	17 Sep 2020 20:59:28

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:05
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:03:44', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a8a03c97-84a2-4d90-8429-ab450ca50c95'	System	11 Sep 2020 21:04:12
User entered 'None (0)'	System	11 Sep 2020 21:04:12

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:03:47', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a8a03c97-84a2-4d90-8429-ab450ca50c95'	System	11 Sep 2020 21:04:12
User entered 'None (0)'	System	11 Sep 2020 21:04:12

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:03:50', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a8a03c97-84a2-4d90-8429-ab450ca50c95'	System	11 Sep 2020 21:04:12
User entered 'None (0)'	System	11 Sep 2020 21:04:12

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:03:52', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a8a03c97-84a2-4d90-8429-ab450ca50c95'	System	11 Sep 2020 21:04:12
User entered 'None (0)'	System	11 Sep 2020 21:04:12

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:03:56', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a8a03c97-84a2-4d90-8429-ab450ca50c95'	System	11 Sep 2020 21:04:12
User entered 'None (0)'	System	11 Sep 2020 21:04:12

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:04:01', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a8a03c97-84a2-4d90-8429-ab450ca50c95'	System	11 Sep 2020 21:04:12
User entered 'None (0)'	System	11 Sep 2020 21:04:12

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:04:04', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a8a03c97-84a2-4d90-8429-ab450ca50c95'	System	11 Sep 2020 21:04:12
User entered 'No (N)'	System	11 Sep 2020 21:04:12

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T16:04:08', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a8a03c97-84a2-4d90-8429-ab450ca50c95'	System	11 Sep 2020 21:04:12
User entered '11 Sep 2020 16:04'	System	11 Sep 2020 21:04:12

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '11 Sep 2020 15:51'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '11 Sep 2020 18:21'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:23:05', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f306b4c7-8966-4f8f-8911-416a4bec8968'	System	12 Sep 2020 01:23:29
User entered 'None (0)'	System	12 Sep 2020 01:23:29

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:23:07', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f306b4c7-8966-4f8f-8911-416a4bec8968'	System	12 Sep 2020 01:23:29
User entered 'None (0)'	System	12 Sep 2020 01:23:29

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:23:10', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f306b4c7-8966-4f8f-8911-416a4bec8968'	System	12 Sep 2020 01:23:29
User entered 'None (0)'	System	12 Sep 2020 01:23:29

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:23:13', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f306b4c7-8966-4f8f-8911-416a4bec8968'	System	12 Sep 2020 01:23:29
User entered 'None (0)'	System	12 Sep 2020 01:23:29

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:23:17', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f306b4c7-8966-4f8f-8911-416a4bec8968'	System	12 Sep 2020 01:23:29
User entered 'None (0)'	System	12 Sep 2020 01:23:29

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:23:20', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f306b4c7-8966-4f8f-8911-416a4bec8968'	System	12 Sep 2020 01:23:29
User entered 'None (0)'	System	12 Sep 2020 01:23:29

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:23:23', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f306b4c7-8966-4f8f-8911-416a4bec8968'	System	12 Sep 2020 01:23:29
User entered 'No (N)'	System	12 Sep 2020 01:23:29

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-11T20:23:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f306b4c7-8966-4f8f-8911-416a4bec8968'	System	12 Sep 2020 01:23:29
User entered '11 Sep 2020 20:23'	System	12 Sep 2020 01:23:29

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '11 Sep 2020 19:16'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 2'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:42', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'c30201a9-894d-49c9-bde5-a1e3ef095e74'	System	13 Sep 2020 02:59:03
User entered 'None (0)'	System	13 Sep 2020 02:59:03

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:44', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'c30201a9-894d-49c9-bde5-a1e3ef095e74'	System	13 Sep 2020 02:59:03
User entered 'None (0)'	System	13 Sep 2020 02:59:03

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:47', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'c30201a9-894d-49c9-bde5-a1e3ef095e74'	System	13 Sep 2020 02:59:03
User entered 'None (0)'	System	13 Sep 2020 02:59:03

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:49', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'c30201a9-894d-49c9-bde5-a1e3ef095e74'	System	13 Sep 2020 02:59:03
User entered 'None (0)'	System	13 Sep 2020 02:59:03

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:51', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'c30201a9-894d-49c9-bde5-a1e3ef095e74'	System	13 Sep 2020 02:59:03
User entered 'None (0)'	System	13 Sep 2020 02:59:03

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:53', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'c30201a9-894d-49c9-bde5-a1e3ef095e74'	System	13 Sep 2020 02:59:03
User entered 'None (0)'	System	13 Sep 2020 02:59:03

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:57', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'c30201a9-894d-49c9-bde5-a1e3ef095e74'	System	13 Sep 2020 02:59:03
User entered 'No (N)'	System	13 Sep 2020 02:59:03

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-12T21:58:59', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'c30201a9-894d-49c9-bde5-a1e3ef095e74'	System	13 Sep 2020 02:59:03
User entered '12 Sep 2020 21:58'	System	13 Sep 2020 02:59:03

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 3'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:20', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '92f5f4f7-7e30-4460-a659-28c253b07b3f'	System	13 Sep 2020 23:59:49
User entered 'None (0)'	System	13 Sep 2020 23:59:49

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:23', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '92f5f4f7-7e30-4460-a659-28c253b07b3f'	System	13 Sep 2020 23:59:49
User entered 'None (0)'	System	13 Sep 2020 23:59:49

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '92f5f4f7-7e30-4460-a659-28c253b07b3f'	System	13 Sep 2020 23:59:49
User entered 'None (0)'	System	13 Sep 2020 23:59:49

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:28', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '92f5f4f7-7e30-4460-a659-28c253b07b3f'	System	13 Sep 2020 23:59:49
User entered 'None (0)'	System	13 Sep 2020 23:59:49

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:30', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '92f5f4f7-7e30-4460-a659-28c253b07b3f'	System	13 Sep 2020 23:59:49
User entered 'None (0)'	System	13 Sep 2020 23:59:49

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:32', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '92f5f4f7-7e30-4460-a659-28c253b07b3f'	System	13 Sep 2020 23:59:49
User entered 'None (0)'	System	13 Sep 2020 23:59:49

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:37', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '92f5f4f7-7e30-4460-a659-28c253b07b3f'	System	13 Sep 2020 23:59:49
User entered 'No (N)'	System	13 Sep 2020 23:59:49

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-13T18:59:39', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '92f5f4f7-7e30-4460-a659-28c253b07b3f'	System	13 Sep 2020 23:59:49
User entered '13 Sep 2020 18:59'	System	13 Sep 2020 23:59:49

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 4'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:55:19', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '70b00101-9458-481f-be7b-6a41885f2e74'	System	14 Sep 2020 23:55:43
User entered 'None (0)'	System	14 Sep 2020 23:55:43

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:55:22', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '70b00101-9458-481f-be7b-6a41885f2e74'	System	14 Sep 2020 23:55:43
User entered 'None (0)'	System	14 Sep 2020 23:55:43

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:55:24', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '70b00101-9458-481f-be7b-6a41885f2e74'	System	14 Sep 2020 23:55:43
User entered 'None (0)'	System	14 Sep 2020 23:55:43

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:55:29', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '70b00101-9458-481f-be7b-6a41885f2e74'	System	14 Sep 2020 23:55:43
User entered 'None (0)'	System	14 Sep 2020 23:55:43

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:55:31', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '70b00101-9458-481f-be7b-6a41885f2e74'	System	14 Sep 2020 23:55:43
User entered 'None (0)'	System	14 Sep 2020 23:55:43

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:55:33', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '70b00101-9458-481f-be7b-6a41885f2e74'	System	14 Sep 2020 23:55:43
User entered 'None (0)'	System	14 Sep 2020 23:55:43

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:55:37', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '70b00101-9458-481f-be7b-6a41885f2e74'	System	14 Sep 2020 23:55:43
User entered 'No (N)'	System	14 Sep 2020 23:55:43

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-14T18:55:42', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '70b00101-9458-481f-be7b-6a41885f2e74'	System	14 Sep 2020 23:55:43
User entered '14 Sep 2020 18:55'	System	14 Sep 2020 23:55:43

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 5'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:18', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'df5a5b3a-3707-4739-b1de-996eb8560ffe'	System	16 Sep 2020 00:49:36
User entered 'None (0)'	System	16 Sep 2020 00:49:36

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:20', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'df5a5b3a-3707-4739-b1de-996eb8560ffe'	System	16 Sep 2020 00:49:36
User entered 'None (0)'	System	16 Sep 2020 00:49:36

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:22', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'df5a5b3a-3707-4739-b1de-996eb8560ffe'	System	16 Sep 2020 00:49:36
User entered 'None (0)'	System	16 Sep 2020 00:49:36

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:24', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'df5a5b3a-3707-4739-b1de-996eb8560ffe'	System	16 Sep 2020 00:49:36
User entered 'None (0)'	System	16 Sep 2020 00:49:36

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'df5a5b3a-3707-4739-b1de-996eb8560ffe'	System	16 Sep 2020 00:49:36
User entered 'None (0)'	System	16 Sep 2020 00:49:36

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:28', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'df5a5b3a-3707-4739-b1de-996eb8560ffe'	System	16 Sep 2020 00:49:36
User entered 'None (0)'	System	16 Sep 2020 00:49:36

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:32', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'df5a5b3a-3707-4739-b1de-996eb8560ffe'	System	16 Sep 2020 00:49:36
User entered 'No (N)'	System	16 Sep 2020 00:49:36

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-15T19:49:35', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'df5a5b3a-3707-4739-b1de-996eb8560ffe'	System	16 Sep 2020 00:49:36
User entered '15 Sep 2020 19:49'	System	16 Sep 2020 00:49:36

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 6'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	11 Sep 2020 20:33:48
User entered 'Day 7'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T15:59:31', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'eea0986e-c749-4425-b56c-9bb5324af053'	System	17 Sep 2020 21:00:37
User entered 'None (0)'	System	17 Sep 2020 21:00:37

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T15:59:35', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'eea0986e-c749-4425-b56c-9bb5324af053'	System	17 Sep 2020 21:00:37
User entered 'None (0)'	System	17 Sep 2020 21:00:37

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T15:59:39', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'eea0986e-c749-4425-b56c-9bb5324af053'	System	17 Sep 2020 21:00:37
User entered 'None (0)'	System	17 Sep 2020 21:00:37

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T16:00:12', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'eea0986e-c749-4425-b56c-9bb5324af053'	System	17 Sep 2020 21:00:37
User entered 'None (0)'	System	17 Sep 2020 21:00:37

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T16:00:15', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'eea0986e-c749-4425-b56c-9bb5324af053'	System	17 Sep 2020 21:00:37
User entered 'None (0)'	System	17 Sep 2020 21:00:37

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T16:00:18', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'eea0986e-c749-4425-b56c-9bb5324af053'	System	17 Sep 2020 21:00:37
User entered 'None (0)'	System	17 Sep 2020 21:00:37

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T16:00:31', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'eea0986e-c749-4425-b56c-9bb5324af053'	System	17 Sep 2020 21:00:37
User entered 'No (N)'	System	17 Sep 2020 21:00:37

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-09-17T16:00:34', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'eea0986e-c749-4425-b56c-9bb5324af053'	System	17 Sep 2020 21:00:37
User entered '17 Sep 2020 16:00'	System	17 Sep 2020 21:00:37

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:33:48

US3042203

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:57:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:16
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:33:48

US3042203

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:38
	(b) (4), (b) (6)	
User signature succeeded.	David Ensز (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Sep 2020 14:17:09
	(b) (4)	

US3042203

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:38
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '18 Sep 2020'	Rylea Gulick (b) (4)	21 Sep 2020 14:17:09
	(b) (4)	

US3042203

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:38
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Sep 2020 14:17:09

US3042203

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:38
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	21 Sep 2020 14:17:09

US3042203

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:38
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	21 Sep 2020 14:17:10
	(b) (4)	

US3042203

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:38
User entered 'I'	(b) (4), (b) (6) System	21 Sep 2020 14:17:10

US3042203

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:44:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	25 Sep 2020 19:49:16
	(b) (4)	

US3042203

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:44:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '25 Sep 2020'	Rylea Gulick (b) (4)	25 Sep 2020 19:49:16
	(b) (4)	

US3042203

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:44:11
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	25 Sep 2020 19:49:16

US3042203

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:44:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	25 Sep 2020 19:49:16
	(b) (4)	

US3042203

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:44:11
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	25 Sep 2020 19:49:17
	(b) (4)	

US3042203

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:44:11
User entered 'I'	(b) (4), (b) (6) System	25 Sep 2020 19:49:17

US3042203

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:23
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	02 Oct 2020 19:49:00

US3042203

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:23
User signature succeeded.	David Enszt (b) (4) (b) (4)	28 Apr 2021 10:23:18
User entered '02 Oct 2020'	Rylea Gulick (b) (4) (b) (4)	02 Oct 2020 19:49:00

US3042203

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:23
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 10:23:18
User entered 'Contact Made (CONTACT MADE)'	Rylea Gulick (b) (4) (b) (4)	02 Oct 2020 19:49:00

US3042203

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:56:23
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	02 Oct 2020 19:49:00
	(b) (4)	

US3042203

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 01:56:23
User signature succeeded.	David Ensz (b) (4) (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	02 Oct 2020 19:49:02

US3042203

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:56:23
	(b) (4), (b) (6)	
User entered '1'	System	02 Oct 2020 19:49:02

US3042203

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Oct 2020 21:49:35
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '16 Oct 2020'	Rylea Gulick (b) (4)	16 Oct 2020 21:49:35
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[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 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	16 Oct 2020 21:49:35
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
User entered 'VISIT3'	(b) (4), (b) (6) System	16 Oct 2020 21:49:35

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Oct 2020 21:49:48
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '16 Oct 2020'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 21:49:48

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '13:00'	Rylea Gulick (b) (4)	16 Oct 2020 21:49:48
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
User entered '16 Oct 2020 13:00'	(b) (4), (b) (6) System	16 Oct 2020 21:49:48

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '36.7' C	Rylea Gulick (b) (4)	16 Oct 2020 21:49:48
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	16 Oct 2020 21:49:48
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	16 Oct 2020 21:49:48
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '77'	Rylea Gulick (b) (4)	16 Oct 2020 21:49:48
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
User entered 'bpm'	(b) (4), (b) (6) System	16 Oct 2020 21:49:48

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '12'	Rylea Gulick (b) (4)	16 Oct 2020 21:49:48
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Oct 2020 21:49:48

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '122'	Rylea Gulick (b) (4)	16 Oct 2020 21:49:48
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
User entered 'mmHg'	(b) (4), (b) (6) System	16 Oct 2020 21:49:48

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '70'	Rylea Gulick (b) (4)	16 Oct 2020 21:49:48
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
User entered 'mmHg'	(b) (4), (b) (6) System	16 Oct 2020 21:49:48

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:54

US3042203

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 04:01:54

US3042203

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 21:49:51

US3042203

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '16 Oct 2020'	Rylea Gulick (b) (4)	16 Oct 2020 21:49:51
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Oct 2020 21:50:01

US3042203

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '16 Oct 2020'	Rylea Gulick (b) (4)	16 Oct 2020 21:50:01
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered '13:10'	Rylea Gulick (b) (4)	16 Oct 2020 21:50:01
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
User entered '16 Oct 2020 13:10'	(b) (4), (b) (6) System	16 Oct 2020 21:50:01

US3042203

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	16 Oct 2020 21:50:02
	(b) (4)	

US3042203

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:01:54
User entered '1'	(b) (4), (b) (6) System	16 Oct 2020 21:50:02

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 64'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-10-16T13:45:41', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '8635a794-f6cd-49dd-86c7-d807c3e7d625'	System	16 Oct 2020 18:46:10
User entered 'No (N)'	System	16 Oct 2020 18:46:10

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-10-16T13:45:51', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '8635a794-f6cd-49dd-86c7-d807c3e7d625'	System	16 Oct 2020 18:46:10
User entered 'No (N)'	System	16 Oct 2020 18:46:10

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-10-16T13:46:06', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '8635a794-f6cd-49dd-86c7-d807c3e7d625'	System	16 Oct 2020 18:46:10
User entered '16 Oct 2020 13:46:06'	System	16 Oct 2020 18:46:10

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 71'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-10-21T09:45:41', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '21b1253e-7a90-4968-b1ee-0a2babbf37a9'	System	21 Oct 2020 14:45:52
User entered 'No (N)'	System	21 Oct 2020 14:45:52

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-10-21T09:45:48', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '21b1253e-7a90-4968-b1ee-0a2babbf37a9'	System	21 Oct 2020 14:45:52
User entered 'No (N)'	System	21 Oct 2020 14:45:52

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-10-21T09:45:52', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '21b1253e-7a90-4968-b1ee-0a2babbf37a9'	System	21 Oct 2020 14:45:52
User entered '21 Oct 2020 09:45:52'	System	21 Oct 2020 14:45:52

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 78'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-11-01T11:07:24', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5969c41b-ddb4-4fa0-9e75-68ad8b08a1ea'	System	01 Nov 2020 17:08:46
User entered 'No (N)'	System	01 Nov 2020 17:08:46

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-11-01T11:07:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5969c41b-ddb4-4fa0-9e75-68ad8b08a1ea'	System	01 Nov 2020 17:08:46
User entered 'No (N)'	System	01 Nov 2020 17:08:46

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-11-01T11:07:29', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5969c41b-ddb4-4fa0-9e75-68ad8b08a1ea'	System	01 Nov 2020 17:08:46
User entered '01 Nov 2020 11:07:29'	System	01 Nov 2020 17:08:46

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
	(b) (4), (b) (6)	
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 92'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-11-14T14:09:53', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '515962fb-d124-441a-a6b3-cdb4088caf64'	System	14 Nov 2020 20:10:14
User entered 'No (N)'	System	14 Nov 2020 20:10:14

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-11-14T14:10:04', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '515962fb-d124-441a-a6b3-cdb4088caf64'	System	14 Nov 2020 20:10:14
User entered 'No (N)'	System	14 Nov 2020 20:10:14

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-11-14T14:10:15', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '515962fb-d124-441a-a6b3-cdb4088caf64'	System	14 Nov 2020 20:10:14
User entered '14 Nov 2020 14:10:15'	System	14 Nov 2020 20:10:14

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:44:00
Data hard unlocked.	(b) (4), (b) (6)	25 Feb 2021 06:09:37
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 04:53:02
Data entry locked.	System	14 Aug 2020 19:35:28
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11
Data entry locked.	System	14 Aug 2020 19:35:28
User entered 'Day 99'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you been exposed to someone with 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 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Please 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 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Please 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 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Please 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 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11
Data entry locked.	System	14 Aug 2020 19:35:28
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 19:35:28

US3042203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:53:11
Data entry locked.	System	14 Aug 2020 19:35:28
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 19:35:28

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2020-11-22T18:53:29', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '907a10b7-2b60-4182-a237-9ed7c7e83831'	System	23 Nov 2020 00:53:40
User entered 'No (N)'	System	23 Nov 2020 00:53:40

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2020-11-22T18:53:33', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '907a10b7-2b60-4182-a237-9ed7c7e83831'	System	23 Nov 2020 00:53:40
User entered 'No (N)'	System	23 Nov 2020 00:53:40

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-11-22T18:53:37', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '907a10b7-2b60-4182-a237-9ed7c7e83831'	System	23 Nov 2020 00:53:40
User entered '22 Nov 2020 18:53:37'	System	23 Nov 2020 00:53:40

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2020-12-02T15:56:32', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '6a2832fc-f12a-47f5-b2d9-9db89918a032'	System	02 Dec 2020 21:57:52
User entered 'Yes (Y)'	System	02 Dec 2020 21:57:52

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2020-12-02T15:56:44', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '6a2832fc-f12a-47f5-b2d9-9db89918a032'	System	02 Dec 2020 21:57:52
User entered 'No (N)'	System	02 Dec 2020 21:57:52

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-02T15:56:52', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '6a2832fc-f12a-47f5-b2d9-9db89918a032'	System	02 Dec 2020 21:57:52
User entered 'No (N)'	System	02 Dec 2020 21:57:52

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-02T15:57:02', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '6a2832fc-f12a-47f5-b2d9-9db89918a032'	System	02 Dec 2020 21:57:52
User entered 'Yes (Y)'	System	02 Dec 2020 21:57:52

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-02T15:57:40', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '6a2832fc-f12a-47f5-b2d9-9db89918a032'	System	02 Dec 2020 21:57:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Dec 2020 21:57:52

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-02T15:57:44', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '6a2832fc-f12a-47f5-b2d9-9db89918a032'	System	02 Dec 2020 21:57:52
User entered '02 Dec 2020 15:57:44'	System	02 Dec 2020 21:57:52

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2020-12-09T09:55:49', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a18657ee-0877-4df0-9293-74e61c0e3522'	System	09 Dec 2020 15:56:34
User entered 'Yes (Y)'	System	09 Dec 2020 15:56:34

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2020-12-09T09:55:53', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a18657ee-0877-4df0-9293-74e61c0e3522'	System	09 Dec 2020 15:56:34
User entered 'No (N)'	System	09 Dec 2020 15:56:34

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-09T09:55:57', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a18657ee-0877-4df0-9293-74e61c0e3522'	System	09 Dec 2020 15:56:34
User entered 'No (N)'	System	09 Dec 2020 15:56:34

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-09T09:56:05', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a18657ee-0877-4df0-9293-74e61c0e3522'	System	09 Dec 2020 15:56:34
User entered 'Yes (Y)'	System	09 Dec 2020 15:56:34

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-09T09:56:22', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a18657ee-0877-4df0-9293-74e61c0e3522'	System	09 Dec 2020 15:56:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Dec 2020 15:56:34

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-09T09:56:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'a18657ee-0877-4df0-9293-74e61c0e3522'	System	09 Dec 2020 15:56:34
User entered '09 Dec 2020 09:56:26'	System	09 Dec 2020 15:56:34

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:21:22
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'NO AE TO ADD' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:37
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 08:41:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-16T11:07:08', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e4471025-4c86-4eb3-99a1-97f171aa4a4d'	System	16 Dec 2020 17:07:37
User entered 'Yes (Y)'	System	16 Dec 2020 17:07:37

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2020-12-16T11:07:13', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e4471025-4c86-4eb3-99a1-97f171aa4a4d'	System	16 Dec 2020 17:07:37
User entered 'No (N)'	System	16 Dec 2020 17:07:37

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-16T11:07:18', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e4471025-4c86-4eb3-99a1-97f171aa4a4d'	System	16 Dec 2020 17:07:37
User entered 'No (N)'	System	16 Dec 2020 17:07:37

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-16T11:07:21', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e4471025-4c86-4eb3-99a1-97f171aa4a4d'	System	16 Dec 2020 17:07:37
User entered 'Yes (Y)'	System	16 Dec 2020 17:07:37

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-16T11:07:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e4471025-4c86-4eb3-99a1-97f171aa4a4d'	System	16 Dec 2020 17:07:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 17:07:37

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-16T11:07:29', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e4471025-4c86-4eb3-99a1-97f171aa4a4d'	System	16 Dec 2020 17:07:37
User entered '16 Dec 2020 11:07:29'	System	16 Dec 2020 17:07:37

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2020-12-21T10:25:39', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e88c7280-008a-4bdd-b269-353a6c9d0b10'	System	21 Dec 2020 16:25:58
User entered 'No (N)'	System	21 Dec 2020 16:25:58

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2020-12-21T10:25:52', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e88c7280-008a-4bdd-b269-353a6c9d0b10'	System	21 Dec 2020 16:25:58
User entered 'No (N)'	System	21 Dec 2020 16:25:58

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-21T10:25:57', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e88c7280-008a-4bdd-b269-353a6c9d0b10'	System	21 Dec 2020 16:25:58
User entered '21 Dec 2020 10:25:57'	System	21 Dec 2020 16:25:58

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2020-12-28T16:44:37', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'b4b2f38e-456e-484a-b127-5368d17fdf71'	System	28 Dec 2020 22:44:49
User entered 'No (N)'	System	28 Dec 2020 22:44:49

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2020-12-28T16:44:42', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'b4b2f38e-456e-484a-b127-5368d17fdf71'	System	28 Dec 2020 22:44:49
User entered 'No (N)'	System	28 Dec 2020 22:44:49

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2020-12-28T16:44:47', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'b4b2f38e-456e-484a-b127-5368d17fdf71'	System	28 Dec 2020 22:44:49
User entered '28 Dec 2020 16:44:47'	System	28 Dec 2020 22:44:49

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-01-03T11:56:10', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '0e0ff59d-eb38-4a38-89f6-3b51e0ffcb7b'	System	03 Jan 2021 17:56:18
User entered 'No (N)'	System	03 Jan 2021 17:56:18

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-01-03T11:56:13', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '0e0ff59d-eb38-4a38-89f6-3b51e0ffcb7b'	System	03 Jan 2021 17:56:18
User entered 'No (N)'	System	03 Jan 2021 17:56:18

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-01-03T11:56:18', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '0e0ff59d-eb38-4a38-89f6-3b51e0ffcb7b'	System	03 Jan 2021 17:56:18
User entered '03 Jan 2021 11:56:18'	System	03 Jan 2021 17:56:18

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-01-10T12:19:34', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '28085f35-8651-447b-83ac-0c2dd23b8719'	System	10 Jan 2021 18:19:48
User entered 'No (N)'	System	10 Jan 2021 18:19:48

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-01-10T12:19:38', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '28085f35-8651-447b-83ac-0c2dd23b8719'	System	10 Jan 2021 18:19:48
User entered 'No (N)'	System	10 Jan 2021 18:19:48

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-01-10T12:19:47', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '28085f35-8651-447b-83ac-0c2dd23b8719' User entered '10 Jan 2021 12:19:47'	System	10 Jan 2021 18:19:48
	System	10 Jan 2021 18:19:48

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-01-17T13:06:36', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '3900a9b8-2a26-4c1b-bfd5-0f3a5b1eba7e'	System	17 Jan 2021 19:06:46
User entered 'No (N)'	System	17 Jan 2021 19:06:46

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-01-17T13:06:39', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '3900a9b8-2a26-4c1b-bfd5-0f3a5b1eba7e'	System	17 Jan 2021 19:06:46
User entered 'No (N)'	System	17 Jan 2021 19:06:46

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-01-17T13:06:48', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '3900a9b8-2a26-4c1b-bfd5-0f3a5b1eba7e' User entered '17 Jan 2021 13:06:48'	System	17 Jan 2021 19:06:46

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-01-26T17:44:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5ed6a33c-6d52-4ecf-b3fa-a6877e13cc3f'	System	27 Jan 2021 00:57:03
User entered 'Yes (Y)'	System	27 Jan 2021 00:57:03

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-01-26T17:44:31', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5ed6a33c-6d52-4ecf-b3fa-a6877e13cc3f'	System	27 Jan 2021 00:57:03
User entered 'No (N)'	System	27 Jan 2021 00:57:03

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-01-26T17:44:35', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5ed6a33c-6d52-4ecf-b3fa-a6877e13cc3f'	System	27 Jan 2021 00:57:03
User entered 'No (N)'	System	27 Jan 2021 00:57:03

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-01-26T17:44:37', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5ed6a33c-6d52-4ecf-b3fa-a6877e13cc3f'	System	27 Jan 2021 00:57:03
User entered 'No (N)'	System	27 Jan 2021 00:57:03

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-01-26T17:44:43', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '5ed6a33c-6d52-4ecf-b3fa-a6877e13cc3f' User entered '26 Jan 2021 17:44:43'	System	27 Jan 2021 00:57:03

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-02-01T15:09:07', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '99aa6689-3cb7-4867-a384-93a45ec5bf96'	System	01 Feb 2021 21:09:13
User entered 'No (N)'	System	01 Feb 2021 21:09:13

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-02-01T15:09:10', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '99aa6689-3cb7-4867-a384-93a45ec5bf96'	System	01 Feb 2021 21:09:13
User entered 'No (N)'	System	01 Feb 2021 21:09:13

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-02-01T15:09:14', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '99aa6689-3cb7-4867-a384-93a45ec5bf96'	System	01 Feb 2021 21:09:13
User entered '01 Feb 2021 15:09:14'	System	01 Feb 2021 21:09:13

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-02-07T07:31:06', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '40d47f74-270e-4f2a-8aa0-aabcaf27c7f4'	System	07 Feb 2021 13:31:16
User entered 'No (N)'	System	07 Feb 2021 13:31:16

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-02-07T07:31:09', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '40d47f74-270e-4f2a-8aa0-aabcaf27c7f4'	System	07 Feb 2021 13:31:16
User entered 'No (N)'	System	07 Feb 2021 13:31:16

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-02-07T07:31:14', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '40d47f74-270e-4f2a-8aa0-aabcaf27c7f4'	System	07 Feb 2021 13:31:16
User entered '07 Feb 2021 07:31:14'	System	07 Feb 2021 13:31:16

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-02-15T07:12:22', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '6eeb1014-6c4f-44b0-be24-4b040dd43549'	System	15 Feb 2021 13:12:33
User entered 'No (N)'	System	15 Feb 2021 13:12:33

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-02-15T07:12:26', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '6eeb1014-6c4f-44b0-be24-4b040dd43549'	System	15 Feb 2021 13:12:33
User entered 'No (N)'	System	15 Feb 2021 13:12:33

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-02-15T07:12:31', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '6eeb1014-6c4f-44b0-be24-4b040dd43549'	System	15 Feb 2021 13:12:33
User entered '15 Feb 2021 07:12:31'	System	15 Feb 2021 13:12:33

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-02-21T15:00:16', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9f8893a7-d25b-475f-a5e1-453d90544363'	System	21 Feb 2021 21:00:39
User entered 'Yes (Y)'	System	21 Feb 2021 21:00:39

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-02-21T15:00:20', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9f8893a7-d25b-475f-a5e1-453d90544363'	System	21 Feb 2021 21:00:39
User entered 'No (N)'	System	21 Feb 2021 21:00:39

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-02-21T15:00:27', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9f8893a7-d25b-475f-a5e1-453d90544363'	System	21 Feb 2021 21:00:39
User entered 'No (N)'	System	21 Feb 2021 21:00:39

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-02-21T15:00:34', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9f8893a7-d25b-475f-a5e1-453d90544363'	System	21 Feb 2021 21:00:39
User entered 'No (N)'	System	21 Feb 2021 21:00:39

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-02-21T15:00:38', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '9f8893a7-d25b-475f-a5e1-453d90544363'	System	21 Feb 2021 21:00:39
User entered '21 Feb 2021 15:00:38'	System	21 Feb 2021 21:00:39

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-02-28T07:05:39-06:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'b9550ddd-1fdf-4ede-83f0-7dd6f1c7376f' User entered 'No (N)'	System	28 Feb 2021 13:05:46

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-02-28T07:05:42-06:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'b9550ddd-1fdf-4ede-83f0-7dd6f1c7376f' User entered 'No (N)'	System	28 Feb 2021 13:05:46

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-02-28T07:05:46-06:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'b9550ddd-1fdf-4ede-83f0-7dd6f1c7376f' User entered '28 Feb 2021 07:05:46'	System	28 Feb 2021 13:05:46
	System	28 Feb 2021 13:05:46

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-03-11T10:11:33-06:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '86f41882-c3cd-4350-b805-3c1fdf9aa0f8'	System	11 Mar 2021 16:11:44
User entered 'No (N)'	System	11 Mar 2021 16:11:44

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-03-11T10:11:36-06:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '86f41882-c3cd-4350-b805-3c1fdf9aa0f8'	System	11 Mar 2021 16:11:44
User entered 'No (N)'	System	11 Mar 2021 16:11:44

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-03-11T10:11:39-06:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '86f41882-c3cd-4350-b805-3c1fdf9aa0f8'	System	11 Mar 2021 16:11:44
User entered '11 Mar 2021 10:11:39'	System	11 Mar 2021 16:11:44

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-03-16T17:40:17-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '6bee39d3-d868-4d07-81a1-a111a51f1537'	System	16 Mar 2021 22:40:28
User entered 'No (N)'	System	16 Mar 2021 22:40:28

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-03-16T17:40:20-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '6bee39d3-d868-4d07-81a1-a111a51f1537'	System	16 Mar 2021 22:40:28
User entered 'No (N)'	System	16 Mar 2021 22:40:28

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-03-16T17:40:26-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '6bee39d3-d868-4d07-81a1-a111a51f1537'	System	16 Mar 2021 22:40:28
User entered '16 Mar 2021 17:40:26'	System	16 Mar 2021 22:40:28

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-03-24T04:21:12-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f338c65b-32ab-40df-b044-9315c350e809'	System	24 Mar 2021 09:22:27
User entered 'No (N)'	System	24 Mar 2021 09:22:27

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-03-24T04:21:47-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f338c65b-32ab-40df-b044-9315c350e809'	System	24 Mar 2021 09:22:27
User entered 'No (N)'	System	24 Mar 2021 09:22:27

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-03-24T04:22:25-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f338c65b-32ab-40df-b044-9315c350e809' User entered '24 Mar 2021 04:22:25'	System	24 Mar 2021 09:22:27
	System	24 Mar 2021 09:22:27

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-03-28T12:30:16-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'd9314c25-2d79-4830-bf53-f6fda7f1fef1'	System	28 Mar 2021 17:30:35
User entered 'No (N)'	System	28 Mar 2021 17:30:35

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-03-28T12:30:22-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'd9314c25-2d79-4830-bf53-f6fda7f1fef1'	System	28 Mar 2021 17:30:35
User entered 'No (N)'	System	28 Mar 2021 17:30:35

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-03-28T12:30:24-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'd9314c25-2d79-4830-bf53-f6fda7f1fef1' User entered '28 Mar 2021 12:30:24'	System	28 Mar 2021 17:30:35
	System	28 Mar 2021 17:30:35

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-04-06T17:46:31-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2252cd32-c170-47de-bc75-1e1e25395913'	System	06 Apr 2021 22:47:21
User entered 'No (N)'	System	06 Apr 2021 22:47:21

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-04-06T17:46:36-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2252cd32-c170-47de-bc75-1e1e25395913'	System	06 Apr 2021 22:47:21
User entered 'No (N)'	System	06 Apr 2021 22:47:21

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-04-06T17:47:17-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: '2252cd32-c170-47de-bc75-1e1e25395913'	System	06 Apr 2021 22:47:21
User entered '06 Apr 2021 17:47:17'	System	06 Apr 2021 22:47:21

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-04-12T19:40:31-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'efbcd74-f387-4853-9151-89533c210ec8'	System	13 Apr 2021 00:40:47
User entered 'No (N)'	System	13 Apr 2021 00:40:47

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-04-12T19:40:35-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'efbcd74-f387-4853-9151-89533c210ec8'	System	13 Apr 2021 00:40:47
User entered 'No (N)'	System	13 Apr 2021 00:40:47

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-04-12T19:40:42-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'efbcd74-f387-4853-9151-89533c210ec8'	System	13 Apr 2021 00:40:47
User entered '12 Apr 2021 19:40:42'	System	13 Apr 2021 00:40:47

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-04-21T18:56:24-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f19d6cac-6c20-45cb-930e-1dc73aad4425'	System	21 Apr 2021 23:56:46
User entered 'No (N)'	System	21 Apr 2021 23:56:46

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-04-21T18:56:27-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f19d6cac-6c20-45cb-930e-1dc73aad4425'	System	21 Apr 2021 23:56:46
User entered 'No (N)'	System	21 Apr 2021 23:56:46

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-04-21T18:56:40-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'f19d6cac-6c20-45cb-930e-1dc73aad4425'	System	21 Apr 2021 23:56:46
User entered '21 Apr 2021 18:56:40'	System	21 Apr 2021 23:56:46

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[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 (bc9e064acbd22b7b)', Time: '2021-04-26T21:15:45-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'c7b52087-8f0d-4739-a56b-e35b20feecf2'	System	27 Apr 2021 02:16:03
User entered 'No (N)'	System	27 Apr 2021 02:16:03

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

Have you been exposed to someone with 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 (bc9e064acbd22b7b)', Time: '2021-04-26T21:15:47-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'c7b52087-8f0d-4739-a56b-e35b20feecf2'	System	27 Apr 2021 02:16:03
User entered 'No (N)'	System	27 Apr 2021 02:16:03

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-04-26T21:15:53-05:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'c7b52087-8f0d-4739-a56b-e35b20feecf2'	System	27 Apr 2021 02:16:03
User entered '26 Apr 2021 21:15:53'	System	27 Apr 2021 02:16:03

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:53:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:53:11

US3042203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:57:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:53:11
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:53:11

US3042203

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:57:51

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)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-02-28T07:05:55-06:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e45b2eb8-b1de-4101-a318-f748f2e08ac0'	System	28 Feb 2021 13:06:08
User entered 'No (N)'	System	28 Feb 2021 13:06:08

US3042203

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:57:51

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:27:55
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bc9e064acbd22b7b)', Time: '2021-02-28T07:06:07-06:00', User OID: 'PatientReportedOutcome (US3042203)', ODM File OID: 'e45b2eb8-b1de-4101-a318-f748f2e08ac0' User entered '28 Feb 2021 07:06:07'	System	28 Feb 2021 13:06:08
	System	28 Feb 2021 13:06:08

US3042203

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	07 Nov 2020 20:31:25

US3042203

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '7 Nov 2020'	(b) (4) Jamie Thompson (b) (4) (b) (4)	07 Nov 2020 20:31:25

US3042203

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	07 Nov 2020 20:31:25

US3042203

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	07 Nov 2020 20:31:25

US3042203

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:24
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	07 Nov 2020 20:31:29

US3042203

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:24
User entered 'I'	(b) (4), (b) (6) System	07 Nov 2020 20:31:29

US3042203

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:51:37

US3042203

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '8 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:51:37

US3042203

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:51:37

US3042203

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:51:37

US3042203

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:51:42

US3042203

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User entered 'I'	(b) (4), (b) (6) System	08 Dec 2020 22:51:42

US3042203

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 16:21:03

US3042203

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '06 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:21:03

US3042203

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:21:03

US3042203

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:21:03

US3042203

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:20:47

US3042203

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User entered 'I'	(b) (4), (b) (6) System	06 Jan 2021 16:20:47

US3042203

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	26 Feb 2021 20:21:53

US3042203

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:22:41
User entered '05 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	26 Feb 2021 20:21:53

US3042203

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Ensز (b) (4)	28 Apr 2021 10:22:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	26 Feb 2021 20:21:53

US3042203

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6)	
	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	26 Feb 2021 20:21:53
	(b) (4)	

US3042203

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	26 Feb 2021 20:21:55

US3042203

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:36
User entered 'I'	(b) (4), (b) (6) System	26 Feb 2021 20:21:55

US3042203

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	26 Feb 2021 20:22:02

US3042203

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '26 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	26 Feb 2021 20:22:02

US3042203

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[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 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	26 Feb 2021 20:22:02

US3042203

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User entered 'VISIT4'	(b) (4), (b) (6) System	26 Feb 2021 20:22:02

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 17:45:26

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:47

US3042203

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 19:42:47

US3042203

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	26 Feb 2021 20:22:06

US3042203

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	26 Feb 2021 20:22:06

US3042203

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	15 Mar 2021 15:52:55

US3042203

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '26 Feb 2021'	(b) (4) Jamie Thompson (b) (4) (b) (4)	15 Mar 2021 15:52:55

US3042203

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '13:20'	(b) (4) Jamie Thompson (b) (4) (b) (4)	15 Mar 2021 15:52:55

US3042203

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User entered '26 Feb 2021 13:20'	(b) (4), (b) (6) System	15 Mar 2021 15:52:55

US3042203

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	26 Feb 2021 20:22:08

US3042203

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:42:47
User entered 'I'	(b) (4), (b) (6) System	26 Feb 2021 20:22:08

US3042203

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:40:10

US3042203

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '6 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:40:10

US3042203

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:40:10

US3042203

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:40:10

US3042203

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:40:17

US3042203

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 13:40:17

US3042203

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

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:11
	(b) (4)	

US3042203

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

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '11 Jan 2021'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:11
	(b) (4)	

US3042203

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

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[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 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Clinic (Clinic)'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:11
	(b) (4)	

US3042203

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

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	12 Jan 2021 17:27:11

US3042203

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:51

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '11 Jan 2021'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:20
	(b) (4)	

US3042203

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:51

[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 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '0'	Rylea Gulick (b) (4)	08 Apr 2021 16:53:01
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:42:43

US3042203

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:51

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:20
	(b) (4)	

US3042203

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:51

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
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) (4), (b) (6)	12 Apr 2021 11:06:35
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 16:53:05
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rylea Gulick (b) (4) (b) (4)	08 Apr 2021 16:53:01
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 16:49:13
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:42:43

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:51

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '11 Jan 2021'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:20
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:51

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Placebo (Placebo)'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:20
	(b) (4)	

US3042203

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:51

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:22:59
User entered 'Placebo (Placebo)'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:20
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:51

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:22:59
User entered 'Placebo (Placebo)'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:20
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:51

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:20
	(b) (4)	

US3042203

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:51

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 17:27:20

US3042203

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

Form: Unblinding

Generated On: 09 Jun 2021 14:57:51

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'I'	(b) (4), (b) (6) System	12 Jan 2021 17:27:20

US3042203

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered missing code ND - Not Done.	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered missing code ND - Not Done.	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User entered empty.	System	12 Jan 2021 17:28:49
DataPoint set to visible.	System	12 Jan 2021 17:27:20

US3042203

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered missing code ND - Not Done.	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered missing code ND - Not Done.	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User entered empty.	System	12 Jan 2021 17:28:49
DataPoint set to visible.	System	12 Jan 2021 17:27:20

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '11 Jan 2021'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '14:56'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered '11 Jan 2021 14:56'	(b) (4), (b) (6) System	12 Jan 2021 17:28:49

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '37.2' C	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '75'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'bpm'	(b) (4), (b) (6) System	12 Jan 2021 17:28:49

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '14'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'breaths/min'	(b) (4), (b) (6) System	12 Jan 2021 17:28:49

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '122'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'mmHg'	(b) (4), (b) (6) System	12 Jan 2021 17:28:49

US3042203

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '70'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'mmHg'	(b) (4), (b) (6) System	12 Jan 2021 17:28:49

US3042203

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered missing code ND - Not Done.	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered missing code ND - Not Done.	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:57:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User entered empty.	System	12 Jan 2021 17:28:49
DataPoint set to visible.	System	12 Jan 2021 17:27:20

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '11 Jan 2021'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '15:56'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered '11 Jan 2021 15:56'	(b) (4), (b) (6)	
	System	12 Jan 2021 17:28:49

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '36.9' C	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Oral (Oral)'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '59'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'bpm'	(b) (4), (b) (6) System	12 Jan 2021 17:28:49

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '14'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'breaths/min'	(b) (4), (b) (6) System	12 Jan 2021 17:28:49

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '130'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'mmHg'	(b) (4), (b) (6) System	12 Jan 2021 17:28:49

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '88'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:49
	(b) (4)	

US3042203

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'mmHg'	(b) (4), (b) (6) System	12 Jan 2021 17:28:49

US3042203

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:54
	(b) (4)	

US3042203

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '11 Jan 2021'	Rylea Gulick (b) (4)	12 Jan 2021 17:28:54
	(b) (4)	

US3042203

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Jan 2021 17:29:04
	(b) (4)	

US3042203

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	12 Jan 2021 17:29:04
	(b) (4)	

US3042203

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered empty.	Rylea Gulick (b) (4)	12 Jan 2021 17:29:04
	(b) (4)	

US3042203

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User entered 'mRNA-1273'	System	12 Jan 2021 17:29:04
DataPoint set to visible.	System	12 Jan 2021 17:27:20

US3042203

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '11 Jan 2021'	Rylea Gulick (b) (4)	12 Jan 2021 17:29:04
	(b) (4)	

US3042203

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '15:18'	Rylea Gulick (b) (4)	12 Jan 2021 17:29:04
	(b) (4)	

US3042203

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered '11 Jan 2021 15:18'	(b) (4), (b) (6) System	12 Jan 2021 17:29:04

US3042203

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Rylea Gulick (b) (4)	12 Jan 2021 17:29:04
	(b) (4)	

US3042203

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'ONCE'	(b) (4), (b) (6) System	12 Jan 2021 17:29:04

US3042203

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

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	12 Jan 2021 17:29:04

US3042203

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:25
	(b) (4)	

US3042203

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '11 Jan 2021'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:25
	(b) (4)	

US3042203

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '14:25'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:25
	(b) (4)	

US3042203

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered '11 Jan 2021 14:25'	(b) (4), (b) (6) System	12 Jan 2021 17:27:25

US3042203

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:30
	(b) (4)	

US3042203

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '11 Jan 2021'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:30
	(b) (4)	

US3042203

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered '14:32'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:30
	(b) (4)	

US3042203

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered '11 Jan 2021 14:32'	(b) (4), (b) (6)	
	System	12 Jan 2021 17:27:30

US3042203

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

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	12 Jan 2021 17:27:32
	(b) (4)	

US3042203

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

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:45:28
User entered 'I'	(b) (4), (b) (6) System	12 Jan 2021 17:27:32

US3042203

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:28
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	20 Jan 2021 14:07:52

US3042203

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:28
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '19 Jan 2021'	(b) (4) Jamie Thompson (b) (4) (b) (4)	20 Jan 2021 14:07:52

US3042203

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:28
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	20 Jan 2021 14:07:52

US3042203

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:28
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered empty.	(b) (4) Jamie Thompson (b) (4) (b) (4)	20 Jan 2021 14:07:52

US3042203

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:28
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	20 Jan 2021 14:07:59

US3042203

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:28
User entered 'I'	(b) (4), (b) (6) System	20 Jan 2021 14:07:59

US3042203

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:32:28
	(b) (4), (b) (6)	
User entered '1'	System	20 Jan 2021 14:07:59
DataPoint set to visible.	System	20 Jan 2021 14:07:59

US3042203

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:46:03

US3042203

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '16 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:46:03

US3042203

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[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 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Clinic (Clinic)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:46:03

US3042203

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'OLD29'	(b) (4), (b) (6) System	16 Feb 2021 22:46:03

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '16 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '13:07'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered '16 Feb 2021 13:07'	(b) (4), (b) (6) System	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '36.9' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '80'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'bpm'	(b) (4), (b) (6) System	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '14'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '112'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'mmHg'	(b) (4), (b) (6) System	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '68'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:57:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'mmHg'	(b) (4), (b) (6) System	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '16 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '14:08'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered '16 Feb 2021 14:08'	(b) (4), (b) (6) System	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '37.0' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '72'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'bpm'	(b) (4), (b) (6) System	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '12'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'breaths/min'	(b) (4), (b) (6) System	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '108'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'mmHg'	(b) (4), (b) (6) System	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '72'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:57:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'mmHg'	(b) (4), (b) (6) System	16 Feb 2021 22:47:33

US3042203

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:45

US3042203

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '16 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:45

US3042203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:53

US3042203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:53

US3042203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:53

US3042203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'mRNA-1273'	(b) (4), (b) (6)	16 Feb 2021 22:47:53
DataPoint set to visible.	System	20 Jan 2021 14:07:59

US3042203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '16 Feb 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:53

US3042203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '13:37'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:53

US3042203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered '16 Feb 2021 13:37'	(b) (4), (b) (6) System	16 Feb 2021 22:47:53

US3042203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Left Arm (LEFT ARM)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:53

US3042203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'ONCE'	(b) (4), (b) (6) System	16 Feb 2021 22:47:53

US3042203

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:57:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	16 Feb 2021 22:47:53

US3042203

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	16 Feb 2021 22:47:55

US3042203

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:10
User entered 'I'	(b) (4), (b) (6) System	16 Feb 2021 22:47:55

US3042203

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:48:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Feb 2021 15:57:23

US3042203

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:48:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered '23 Feb 2021'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Feb 2021 15:57:23

US3042203

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:48:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Feb 2021 15:57:23

US3042203

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:57:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:48:50
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:23:18
	(b) (4)	
User entered empty.	Jamie Thompson (b) (4)	23 Feb 2021 15:57:23
	(b) (4)	

US3042203

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:48:50
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:23:18
User entered 'Yes (Y)'	(b) (4) Jamie Thompson (b) (4) (b) (4)	23 Feb 2021 15:57:57

US3042203

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:57:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:48:50
User entered '1'	(b) (4), (b) (6) System	23 Feb 2021 15:57:57

US3042203

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:05

US3042203

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '15 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:05

US3042203

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

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 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4) System	15 Mar 2021 19:03:08
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:08
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	15 Mar 2021 19:03:05
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:05

US3042203

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:57:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User entered 'OLD57'	(b) (4), (b) (6) System	15 Mar 2021 19:03:05

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '15 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '13:05'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User entered '15 Mar 2021 13:05'	(b) (4), (b) (6) System	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '37.3' C	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Oral (Oral)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '96'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User entered 'bpm'	(b) (4), (b) (6) System	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '12'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '130'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User entered 'mmHg'	(b) (4), (b) (6) System	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '88'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User entered 'mmHg'	(b) (4), (b) (6) System	15 Mar 2021 19:03:18

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
	(b) (4), (b) (6)	

US3042203

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:57:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
	(b) (4), (b) (6)	

US3042203

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'No (N)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:29

US3042203

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:57:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered empty.	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:29

US3042203

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered 'Yes (Y)'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:45

US3042203

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '15 Mar 2021'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:45

US3042203

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User signature succeeded.	(b) (4), (b) (6) David Enszt (b) (4)	28 Apr 2021 10:22:41
User entered '13:12'	(b) (4) Rylea Gulick (b) (4) (b) (4)	15 Mar 2021 19:03:45

US3042203

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:34
User entered '15 Mar 2021 13:12'	(b) (4), (b) (6) System	15 Mar 2021 19:03:45

US3042203

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:19
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:57:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	01 Dec 2020 19:21:40
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	11 Sep 2020 22:51:36
	(b) (4)	

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:02:26
User entered	System	02 Dec 2020 18:02:22
'USA-US052-2020-mRNA-1273-P301000022'		
User entered 'New'	(b) (4), (b) (6)	02 Dec 2020 18:02:22

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGt: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pneumothorax, LLT: Collapse of lung - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 11:01:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 11:01:29
Data point term sent to Coder	System	01 Dec 2020 19:23:12
User entered 'RIGHT COLLAPSED LUNG'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered '30 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 17:31:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 21:50:48
User entered 'No (N)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 21:49:36
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
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)	12 Jan 2021 20:38:21
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'END DATE PROVIDED' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 17:31:50
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	12 Jan 2021 17:31:29
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	12 Jan 2021 17:31:29
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	12 Jan 2021 17:31:08
User entered '14 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 17:31:08
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)	21 Dec 2020 14:01:21
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)	16 Dec 2020 15:54:39
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 21:50:48

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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 21:50:48
User entered empty; reason for change Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 21:50:48
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'entry updated' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 21:50:24
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 21:49:36
User entered '14 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 21:49:36
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)	09 Dec 2020 18:45:59
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User closed query 'PV Query: Please provide the severity of right collapsed lung.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 02:25:07
Query 'PV Query: Please provide the severity of right collapsed lung.' answered with 'ENTRY UPDATED' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 16:57:03
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 16:56:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 16:56:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 16:56:55
User opened query 'PV Query: Please provide the severity of right collapsed lung.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:45:15
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 19:22:28
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	01 Dec 2020 19:22:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:46
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	01 Dec 2020 19:22:28
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered '0'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered '0'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

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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 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 08:16:07
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'SUBJECT IS STILL CURRENTLY HOSPITALIZED' (Site from System).	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:23:15
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	01 Dec 2020 19:22:28
User entered 'I'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User closed query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 14:58:32
Query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization.' answered with 'UNSURE IF ANY EXAMINATION FOR SARS-COV-2 WAS PERFORMED' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 22:12:39
User opened query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 21:08:24
User entered '30 Nov 2020'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:58:05
User closed query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 02:25:09
Query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'HOPSITAL RECORDS ARE STILL BEING OBTAINED' (Site from Safety).	Rylea Gulick (b) (4)	22 Jan 2021 16:57:17
	(b) (4)	
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 15:55:06
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'entry updated' (Site from Safety).	Rylea Gulick (b) (4)	15 Dec 2020 21:49:43
	(b) (4)	
User entered '14 Dec 2020' reason for change: Data Entry Error	Rylea Gulick (b) (4)	15 Dec 2020 21:49:22
	(b) (4)	
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)	09 Dec 2020 18:49:33
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:44:23
User entered empty.	Rylea Gulick (b) (4)	01 Dec 2020 19:22:28
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered '0'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered '0'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered '0'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. ' canceled (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 16:25:32
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:58:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 21:58:59
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	04 Dec 2020 21:58:59
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 18:54:11
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 19:22:28
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	22 Jan 2021 16:56:55
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 16:25:33
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:58:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 21:58:59
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jessica Knight (b) (4) (b) (4)	04 Dec 2020 21:58:59
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 18:54:15
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 19:22:28
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered 'Not Applicable (NOT APPLICABLE)'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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None

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Dec 2020 20:45:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Dec 2020 22:05:08
User entered '0'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered '0'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered '1' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 20:45:48
User entered '0' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	15 Dec 2020 22:05:08
User entered '1'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
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)	12 Jan 2021 20:38:35
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 UPDATD' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 17:32:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	12 Jan 2021 17:31:29
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:00:46
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)	16 Dec 2020 15:57:01
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)	15 Dec 2020 21:52:15
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 18:45:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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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 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:05
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 16:27:42
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 16:27:34
User closed query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 16:27:25
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. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 16:27:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
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. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' answered with 'MEDICAL RECORDS UNABLE TO BE OBTAINED.' (Site from Safety).	Rylea Gulick (b) (4)	02 Mar 2021 22:07:31
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. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' answered with 'MEDICAL RECORDS UNABLE TO BE OBTAINED.' (Site from Safety).	Rylea Gulick (b) (4)	02 Mar 2021 22:07:20
Query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' answered with 'MEDICAL RECORDS UNABLE TO BE OBTAINED.' (Site from Safety).	Rylea Gulick (b) (4)	02 Mar 2021 22:07:12
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' answered with 'MEDICAL RECORDS UNABLE TO BE OBTAINED' (Site from Safety).	Rylea Gulick (b) (4)	02 Mar 2021 22:06:54

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: 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. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:45:00
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. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:44:42
User opened query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:44:34
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:44:29

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:44:25
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. IF medical records were unable to be obtained, please state "Medical Records unable to be obtained" in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 19:44:20
User closed query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 21:21:33
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 21:21:31
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 21:21:28

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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)	03 Feb 2021 21:21:23
Query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization.' answered with 'UNKNOWN AS HOSPITAL RECORDS WERE NOT OBTAINED' (Site from Safety).	Rylea Gulick (b) (4)	02 Feb 2021 23:37:18
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'UNKNOWN AS HOSPITAL RECORDS WERE NOT OBTAINED.' (Site from Safety).	Rylea Gulick (b) (4)	02 Feb 2021 23:36:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'UNKNOWN AS HOSPITAL RECORDS WERE NOT OBTAINED.' (Site from Safety).	Rylea Gulick (b) (4)	02 Feb 2021 23:36:48
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 'UNKNOWN AS HOSPITAL RECORDS WERE NOT OBTAINED.' (Site from Safety).	Rylea Gulick (b) (4)	02 Feb 2021 23:36:36
User opened query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 17:31:05

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US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

[Narrative](#)

Audit	User	Time (GMT)
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)	01 Feb 2021 17:30:58
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 17:30:48
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)	01 Feb 2021 17:29:51
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:00:54
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:00:53
User closed query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:00:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

[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)	01 Feb 2021 15:00:46
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 'unknown as hospital discharge papers are being obtained' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	29 Jan 2021 21:03:49
Query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization.' answered with 'unclear as hospital discharge papers are being obtained' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	29 Jan 2021 21:03:33
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'hospital discharge papers are still being obtained' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	29 Jan 2021 21:03:19
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'hospital discharge papers are still being obtained' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	29 Jan 2021 21:03:06

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:51

[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)	29 Jan 2021 16:26:22
User opened query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 16:26:06
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 16:25:58
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)	29 Jan 2021 14:58:39
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 14:58:36
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'UNKNOWN AS HOSPITAL RECORDS ARE STILL BEING OBTAINED.' (Site from Safety).	Rylea Gulick (b) (4) (b) (4)	28 Jan 2021 22:13:12

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:57:51

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'UNKNOWN AS HOSPITAL RECORDS ARE STILL BEING OBTAINED.' (Site from Safety).	Rylea Gulick (b) (4)	28 Jan 2021 22:13:00
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)	28 Jan 2021 21:07:49
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)	28 Jan 2021 21:07:34
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)	28 Jan 2021 21:07:23
User closed query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 02:25:16
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)	25 Jan 2021 02:25:14
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)	25 Jan 2021 02:25:12

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization.' answered with 'HOSPITAL RECORDS ARE STILL BEING OBTAINED.' (Site from Safety).	Rylea Gulick (b) (4)	22 Jan 2021 16:58:20
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'HOSPITAL RECORDS ARE STILL BEING OBTAINED.' (Site from Safety).	Rylea Gulick (b) (4)	22 Jan 2021 16:58:11
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 'HOSPITAL RECORDS ARE STILL BEING OBTAINED.' (Site from Safety).	Rylea Gulick (b) (4)	22 Jan 2021 16:58:02
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)	19 Jan 2021 14:02:43
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)	19 Jan 2021 14:01:45
User opened query 'PV Query: Please clarify whether any examination of SARS-CoV-2 was performed during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:02:18
User closed query 'PV Query: Please clarify medical history of "left partial lobectomy".' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 15:57:19
Query 'PV Query: Please clarify medical history of "left partial lobectomy".' answered with 'subject had left partial lobectomy in 2017.' (Site from Safety).	Rylea Gulick (b) (4)	15 Dec 2020 21:52:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

[Narrative](#)

Audit	User	Time (GMT)
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)	09 Dec 2020 18:48:58
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)	09 Dec 2020 18:44:44
User opened query 'PV Query: Please clarify medical history of "left partial lobectomy".' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:43:45
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Dec 2020 19:23:41
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	01 Dec 2020 19:23:41
User entered 'SUBJECT WAS HOSPITALIZED FOR A RIGHT COLLAPSED LUNG.' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:23:41
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Dec 2020 19:22:46
User entered empty.	Rylea Gulick (b) (4) (b) (4)	01 Dec 2020 19:22:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 19:22:46
User entered '0'	System	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered 'I'	System	01 Dec 2020 19:22:28

US3042203

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '0'	System	01 Dec 2020 19:22:28

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:19
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:58:20
User entered 'Yes (Y)'	Rylea Gulick (b) (4)	15 Aug 2020 13:36:41
	(b) (4)	

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
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)	04 Sep 2020 05:03:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 05:03:52
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:49:11 02 Sep 2020 23:48:13
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)	16 Aug 2020 09:12:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 09:12:14
Data point term sent to Coder User entered 'GABAPENTIN'	System Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:31 15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
Query 'Per DM CLR: Please review Indication and please update to further the location of Left Side and update to specify the type of Neuropathy (e.g. Motor or Sensory). Please update as appropriate 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 10:11:40
User opened query 'Per DM CLR: Please review Indication and please update to further the location of Left Side and update to specify the type of Neuropathy (e.g. Motor or Sensory). Please update as appropriate and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 06:12:37
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 11:07:32
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.'	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:48:25
' answered with 'CONDITION IS UPDATED TO MATCH MED HISTORY' (Site from DM).		
User entered 'LEFT SIDE NEUROPATHY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:48:13
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 09:23:23
User entered 'LEFT SIDE NERVE DAMAGE'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '600'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'twice daily (BID)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed 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).	(b) (4), (b) (6)	16 Aug 2020 17:58:02
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)	15 Aug 2020 13:37:14
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	15 Aug 2020 13:37:03
User entered 'UN UNK 2018'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '0'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '2'	System	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 13:37:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
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) (b) (4)	15 Aug 2020 13:39:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:39:16
Data point term sent to Coder	System	15 Aug 2020 13:38:31
User entered 'ATORVASTATIN'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'HYPERCHOLESTEROLEMIA'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 16:32:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 16:32:35
User entered '40' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Aug 2020 16:32:35
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 13:37:40
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed 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).	(b) (4), (b) (6)	16 Aug 2020 17:58:06
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)	15 Aug 2020 13:37:49
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	15 Aug 2020 13:37:40
User entered 'UN UNK 2018'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '0'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 13:37:40

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:03:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 19:03:23
Data point term sent to Coder	System	15 Aug 2020 13:38:31
User entered 'SEREQUEL'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'INSOMNIA'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '100'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed 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).	(b) (4), (b) (6)	16 Aug 2020 17:58:10
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)	15 Aug 2020 13:38:13
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	15 Aug 2020 13:38:08
User entered 'UN UNK 2016'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '0'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 13:38:08

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:40:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:40:16
Data point term sent to Coder	System	15 Aug 2020 13:39:32
User entered 'SYMBICORT'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 16:32:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 16:32:52
User entered '160/4.5' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Aug 2020 16:32:52
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 13:38:44
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 16:32:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 16:32:52
User entered 'ug (ug)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Aug 2020 16:32:52
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 13:38:44
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'twice daily (BID)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed 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).	(b) (4), (b) (6)	16 Aug 2020 17:58:16
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)	15 Aug 2020 13:38:59
	(b) (4)	
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	15 Aug 2020 13:38:44
User entered 'UN UNK 2015'	Rylea Gulick (b) (4)	15 Aug 2020 13:38:44
	(b) (4)	

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '0'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '2'	System	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 13:38:44

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM BROMIDE, PRODUCTSYNONYM: SPIRIVA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:50:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 23:50:57
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:50:12 02 Sep 2020 23:49:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM BROMIDE, PRODUCTSYNONYM: SPIRIVA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:40:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:40:16
Data point term sent to Coder User entered 'SPIRIVA'	System Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:34 15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 16:33:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 16:33:02
User entered '18' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Aug 2020 16:33:02
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 13:39:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 16:33:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 16:33:02
User entered 'ug (ug)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Aug 2020 16:33:02
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 13:39:24
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 11:08:05
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'ROUTE UPDATED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:49:23
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Sep 2020 23:49:19
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 09:24:01
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed 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).	(b) (4), (b) (6)	16 Aug 2020 17:58:20
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)	15 Aug 2020 13:39:31
	(b) (4)	
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	15 Aug 2020 13:39:24
User entered 'UN UNK 2015'	Rylea Gulick (b) (4)	15 Aug 2020 13:39:24
	(b) (4)	

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '0'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 13:39:24

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:41:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 13:41:16
Data point term sent to Coder	System	15 Aug 2020 13:40:35
User entered 'ZYRTEC'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'SEASONAL ALLERGIES'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 16:33:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 16:33:11
User entered '10' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Aug 2020 16:33:11
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 13:39:59
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 16:33:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 16:33:11
User entered 'mg (mg)' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Aug 2020 16:33:11
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 13:39:59
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed 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).	(b) (4), (b) (6)	16 Aug 2020 17:58:25
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)	15 Aug 2020 13:40:05
	(b) (4)	
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	15 Aug 2020 13:39:59
User entered 'UN Apr 2020'	Rylea Gulick (b) (4)	15 Aug 2020 13:39:59
	(b) (4)	

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '0'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 13:39:59

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VORTIOXETINE HYDROBROMIDE, PRODUCTSYNONYM: TRINTELLIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:34:43
Data point term sent to Coder User entered 'TRINTELLIX'	System Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:33 18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 15:15:32
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'ENTRY HAS BEEN ADDED' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:17:04
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:07:19
User entered 'DEPRESSION'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '20'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'once daily (QD)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'UN May 2020'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '0'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Dec 2020 16:51:13

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: NABUMETONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:41:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:41:44
Data point term sent to Coder	System	18 Dec 2020 16:52:34
User entered 'NABUMETONE'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'NEUROPATHY'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '500'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'UN UNK 2018'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '0'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 16:51:39

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 16:19:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 16:19:55
Data point term sent to Coder Coding entries removed.	System Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:17:47 13 Jan 2021 22:17:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:35:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:35:13
Data point term sent to Coder User entered 'IBUPROFEN'	System Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:34 18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User closed query 'Per DM CLR: Please update the condition to include the location of Post-Procedural Pain (back, arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 15:17:16
Query 'Per DM CLR: Please update the condition to include the location of Post-Procedural Pain (back, arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' answered with 'ENTRY UPDATD' (Site from DM).	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:17:29
User entered 'POST-PROCEDURAL PAIN-BACK' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	13 Jan 2021 22:17:24
User opened query 'Per DM CLR: Please update the condition to include the location of Post-Procedural Pain (back, arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:07:36
User entered 'POST-PROCEDURAL PAIN'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '800'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'mg (mg)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'as needed (PRN)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Oral (ORAL)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '14 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered '0'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'Yes (Y)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Ensz (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:58:41
User entered 'No (N)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 16:52:03

US3042203

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:57:51

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:19
	(b) (4), (b) (6)	
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:59:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Rylea Gulick (b) (4)	18 Dec 2020 16:53:41
	(b) (4)	
User entered 'No (N)'	Rylea Gulick (b) (4)	15 Aug 2020 13:40:11
	(b) (4)	

US3042203

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:57:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:59:25
User entered '09 Dec 2020'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:54:43

US3042203

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:57:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:59:25
User entered 'PLEURODESIS' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:55:07
User entered 'PLEUROLDESIS'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:54:43

US3042203

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:57:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:59:25
User entered 'Adverse Event (AE)'	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:54:43

US3042203

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:57:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:59:25
User entered empty.	Rylea Gulick (b) (4) (b) (4)	18 Dec 2020 16:54:43

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'USA-US052-2020-MRNA-1273-P301000022'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:38:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:04
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:38:11
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Meagan'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:00
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:19
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:58:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Miller'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:05
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:40
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User opened query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 23:55:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '330 dakota dunes suite400'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'North sioux'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'IA'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '57049'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 16:48:49
User entered 'US'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '6'	System	25 Jan 2021 02:25:32
User entered '5'	System	12 Jan 2021 20:38:58
User entered '4'	System	21 Dec 2020 16:26:29
User entered '3'	System	16 Dec 2020 15:59:34
User entered '2'	System	06 Dec 2020 16:49:01
User entered '1'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'USA-US052-2020-MRNA-1273-P301000022'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:38:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:04
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:38:11
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Meagan'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:00
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:19
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:58:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Miller'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:05
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:40
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User opened query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 23:55:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '330 dakota dunes suite400'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'North sioux'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'IA'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '57049'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 16:48:49
User entered 'US'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '6'	System	25 Jan 2021 02:25:32
User entered '5'	System	12 Jan 2021 20:38:58
User entered '4'	System	21 Dec 2020 16:26:29
User entered '3'	System	16 Dec 2020 15:59:34
User entered '2'	System	06 Dec 2020 16:49:01
User entered '1'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
User entered '02/Dec/2020 13:03'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:57:51

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 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 16:48:49
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'USA-US052-2020-MRNA-1273-P301000022'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Death

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:38:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:04
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:38:11
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Meagan'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:00
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:19
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:58:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Miller'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:05
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:40
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User opened query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 23:55:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '330 dakota dunes suite400'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'North sioux'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'IA'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '57049'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 16:48:49
User entered 'US'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '6'	System	25 Jan 2021 02:25:32
User entered '5'	System	12 Jan 2021 20:38:58
User entered '4'	System	21 Dec 2020 16:26:29
User entered '3'	System	16 Dec 2020 15:59:34
User entered '2'	System	06 Dec 2020 16:49:01
User entered '1'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
User entered '06/Dec/2020 16:49'	System	06 Dec 2020 16:49:01

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:57:51

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 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:59:08
User entered 'I'	(b) (4), (b) (6)	06 Dec 2020 16:49:01

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'USA-US052-2020-MRNA-1273-P301000022'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:38:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:04
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:38:11
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Meagan'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:00
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:19
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:58:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Miller'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:05
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:40
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User opened query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 23:55:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '330 dakota dunes suite400'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'North sioux'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'IA'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '57049'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 16:48:49
User entered 'US'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '6'	System	25 Jan 2021 02:25:32
User entered '5'	System	12 Jan 2021 20:38:58
User entered '4'	System	21 Dec 2020 16:26:29
User entered '3'	System	16 Dec 2020 15:59:34
User entered '2'	System	06 Dec 2020 16:49:01
User entered '1'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
User entered '16/Dec/2020 10:59'	System	16 Dec 2020 15:59:34

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:57:51

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 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 16:26:16
User entered 'I'	(b) (4), (b) (6)	16 Dec 2020 15:59:34

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'USA-US052-2020-MRNA-1273-P301000022'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:38:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:04
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:38:11
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Meagan'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:00
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:19
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:58:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Miller'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:05
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:40
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User opened query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 23:55:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '330 dakota dunes suite400'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'North sioux'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'IA'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '57049'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 16:48:49
User entered 'US'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '6'	System	25 Jan 2021 02:25:32
User entered '5'	System	12 Jan 2021 20:38:58
User entered '4'	System	21 Dec 2020 16:26:29
User entered '3'	System	16 Dec 2020 15:59:34
User entered '2'	System	06 Dec 2020 16:49:01
User entered '1'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
User entered '21/Dec/2020 16:26'	System	21 Dec 2020 16:26:29

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:57:51

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 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 20:38:49
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 16:26:29

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'USA-US052-2020-MRNA-1273-P301000022'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:38:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:04
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:38:11
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Meagan'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:00
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:19
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:58:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Miller'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:05
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:40
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User opened query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 23:55:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '330 dakota dunes suite400'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'North sioux'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'IA'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '57049'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 16:48:49
User entered 'US'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '6'	System	25 Jan 2021 02:25:32
User entered '5'	System	12 Jan 2021 20:38:58
User entered '4'	System	21 Dec 2020 16:26:29
User entered '3'	System	16 Dec 2020 15:59:34
User entered '2'	System	06 Dec 2020 16:49:01
User entered '1'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
User entered '12/Jan/2021 15:38'	System	12 Jan 2021 20:38:58

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:57:51

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 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:25:23
User entered 'I'	(b) (4), (b) (6)	12 Jan 2021 20:38:58

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'USA-US052-2020-MRNA-1273-P301000022'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Yes (Y)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'No (N)'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:38:57
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:04
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'DAVID' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:38:11
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Meagan'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Should be PI name' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:00
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Should be PI name' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:19
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User entered 'ENSZ' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:04:59
User opened query 'Should be PI name' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 22:58:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'Miller'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
User closed query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:39:05
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:56:56
Query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' answered with 'ENTRY UPDATED' (Site from CRA).	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:40
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '4802 SUNNYBROOK DRIVE' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User opened query 'Please update the address to current one for any SAE that have occurred after Nov 1, 2020' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 23:55:07
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '330 dakota dunes suite400'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered 'SIOUX CITY' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'North sioux'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered 'IA'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Un-reviewed for Safety.	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
User entered '51106' reason for change: Data Entry Error	Rylea Gulick (b) (4) (b) (4)	02 Mar 2021 22:05:35
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:03:12
User entered '57049'	System	02 Dec 2020 18:02:22

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 16:48:49
User entered 'US'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User entered '6'	System	25 Jan 2021 02:25:32
User entered '5'	System	12 Jan 2021 20:38:58
User entered '4'	System	21 Dec 2020 16:26:29
User entered '3'	System	16 Dec 2020 15:59:34
User entered '2'	System	06 Dec 2020 16:49:01
User entered '1'	System	02 Dec 2020 18:03:17

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:57:51

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

Audit	User	Time (GMT)
User signature succeeded.	David Enszt (b) (4)	28 Apr 2021 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
User entered '24/Jan/2021 21:25'	System	25 Jan 2021 02:25:32

US3042203

Folder: SAE USA-US052-2020-MRNA-1273-P301000022

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:57:51

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 10:22:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 15:56:56
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 02:25:32