

US3272085 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:25:43

All time stamps listed in this document are displayed in GMT

US3272085

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

Participant ID

US3272085

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

US3272085

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 14:53:33

Generated On: 09 Jun 2021 16:25:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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) 09 Apr 2021 14:53:32

Generated On: 09 Jun 2021 16:25:43

Date of Birth (MMM yyyy)	(b) (6)	1961
Age		58
Age Units		YEARS
Age (Derived)		58
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) 09 Apr 2021 14:53:32

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Date of Informed Consent (*dd MMM yyyy*) 07 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input 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

US3272085

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Apr 2021 14:53:32

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Apr 2021 14:53:32

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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) 09 Apr 2021 14:53:32

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Condition	PENICILLIN ALLERGY/ ANAPHYLAXIS
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 14:53:32

Generated On: 09 Jun 2021 16:25:43

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Apr 2021 14:53:32

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Apr 2021 14:53:32

Generated On: 09 Jun 2021 16:25:43

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Apr 2021 14:53:32

Generated On: 09 Jun 2021 16:25:43

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Apr 2021 14:53:32

Generated On: 09 Jun 2021 16:25:43

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Apr 2021 14:53:32

Generated On: 09 Jun 2021 16:25:43

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 09 Apr 2021 14:53:32

Generated On: 09 Jun 2021 16:25:43

Condition	AMPLATZER CRIBRIFORM OCCLUDER DEVICE
Start date (dd MMM yyyy)	29 MAY 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 09 Apr 2021 14:53:32

Generated On: 09 Jun 2021 16:25:43

Condition	PATENT FORAMEN OVALE
Start date (dd MMM yyyy)	UN UNK 2011
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)	29 MAY 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	MAY 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 09 Apr 2021 14:53:32

Generated On: 09 Jun 2021 16:25:43

Condition	TRANSIENT ISCHEMIC ATTACKS
Start date (dd MMM yyyy)	UN UNK 2007
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)	29 MAY 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	MAY 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 09 Apr 2021 14:53:32

Generated On: 09 Jun 2021 16:25:43

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 09 Apr 2021 14:53:32

Generated On: 09 Jun 2021 16:25:43

Condition	DIARRHEA
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: Vital Signs

Data signed: (b) (4) 09 Apr 2021 14:53:33

Generated On: 09 Jun 2021 16:25:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 15:30
Height (xxx.x)	179 cm
Weight (xxx.x)	89.4 kg
BMI (xxx.x)	27.90175 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 14:53:32

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 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) 09 Apr 2021 14:53:32

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Apr 2021 14:53:32

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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) 29 Apr 2021 17:16:53

Generated On: 09 Jun 2021 16:25:43

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

Visit date (dd MMM yyyy)	07 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Apr 2021 17:16:53

Generated On: 09 Jun 2021 16:25:43

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 143222

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 17:16:53

Generated On: 09 Jun 2021 16:25:43

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) 29 Apr 2021 17:16:53

Generated On: 09 Jun 2021 16:25:43

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)	07 AUG 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 15:30
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 17:16:53

Generated On: 09 Jun 2021 16:25:43

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)	07 AUG 2020
Time of assessment (00:00-23:59)	17:27 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 17:27
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 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: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:16:53

Generated On: 09 Jun 2021 16:25:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 17:16:53

Generated On: 09 Jun 2021 16:25:43

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) 07 AUG 2020

What was the treatment time? (00:00-23:59) 16:51 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 16:51

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) 29 Apr 2021 17:16:53

Generated On: 09 Jun 2021 16:25:43

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

Collection date (dd MMM yyyy)	07 AUG 2020
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Collection time (00:00-23:59)	15:50 (24 HR)
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Collection date and time (derived)	07 AUG 2020 15:50
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Collection date (dd MMM yyyy)			7 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:47	7 AUG 2020 15:47
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 17:25

PC Open Date & Time

07 AUG 2020 17:11

PC Close Date & Time

07 AUG 2020 19:41

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °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	07 AUG 2020 23:08
PC Open Date & Time	07 AUG 2020 20:36
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

08 AUG 2020 20:58

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 17:31

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 22:11

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

97.6 °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

11 AUG 2020 21:09

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

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 ☒

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 AUG 2020 22:27

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 21:02

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

07 AUG 2020 17:34

PC Open Date & Time

07 AUG 2020 17:11

PC Close Date & Time

07 AUG 2020 19:41

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

07 AUG 2020 23:09

PC Open Date & Time

07 AUG 2020 20:36

PC Close Date & Time

08 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

08 AUG 2020 20:59

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

09 AUG 2020 17:31

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

10 AUG 2020 22:12

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

11 AUG 2020 21:10

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

12 AUG 2020 22:29

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

13 AUG 2020 21:02

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 17:35
PC Open Date & Time	07 AUG 2020 17:11
PC Close Date & Time	07 AUG 2020 19:41

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 23:09
PC Open Date & Time	07 AUG 2020 20:36
PC Close Date & Time	08 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

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 ☒

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 20:59
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

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)

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 17:32
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

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 ☒

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 22:12
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

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 ☒

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

61 of 2556

EAB) (1725)

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 22:29
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

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 ☒

PRODUCTION RELEASE (v12.003

63 of 2556

EAB) (1725)

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 21:03
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3272085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 AUG 2020 00:02
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3272085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3272085

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:16:54

Generated On: 09 Jun 2021 16:25:43

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

Visit date (dd MMM yyyy)	04 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 17:16:54

Generated On: 09 Jun 2021 16:25:43

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)	04 SEP 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 14:15
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 17:16:54

Generated On: 09 Jun 2021 16:25:43

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	15:40 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 15:40
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3272085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:16:54

Generated On: 09 Jun 2021 16:25:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 17:16:54

Generated On: 09 Jun 2021 16:25:43

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) 04 SEP 2020

What was the treatment time? (00:00-23:59) 15:09 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 15:09

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

US3272085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:16:54

Generated On: 09 Jun 2021 16:25:43

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

Collection date (dd MMM yyyy)	4 SEP 2020
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Collection time (00:00-23:59)	14:31 (24 HR)
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Collection date and time (derived)	4 SEP 2020 14:31
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US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 17:16:54

Generated On: 09 Jun 2021 16:25:43

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:24	04 SEP 2020 14:24
Nasopharyngeal Swab 2	No		

US3272085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:16:54

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 15:43

PC Open Date & Time

04 SEP 2020 15:29

PC Close Date & Time

04 SEP 2020 17:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °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	05 SEP 2020 02:30
PC Open Date & Time	04 SEP 2020 18:54
PC Close Date & Time	05 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 21:19

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

98.1 °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

06 SEP 2020 21:53

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

98.1 °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

08 SEP 2020 00:39

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 20:27

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 00:00

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

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.

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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

10 SEP 2020 18:35

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

04 SEP 2020 15:43

PC Open Date & Time

04 SEP 2020 15:29

PC Close Date & Time

04 SEP 2020 17:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

05 SEP 2020 02:30

PC Open Date & Time

04 SEP 2020 18:54

PC Close Date & Time

05 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

05 SEP 2020 21:19

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

06 SEP 2020 21:54

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

08 SEP 2020 00:39

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

08 SEP 2020 20:27

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

10 SEP 2020 00:00

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

10 SEP 2020 18:35

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 15:44
PC Open Date & Time	04 SEP 2020 15:29
PC Close Date & Time	04 SEP 2020 17:59

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 02:31
PC Open Date & Time	04 SEP 2020 18:54
PC Close Date & Time	05 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

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 ☒

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:20
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

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 ☒

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 21:54
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

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 ☒

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 00:40
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

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 ☒

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 20:28
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

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 ☒

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 00:01
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

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 ☒

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 18:35
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3272085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3272085

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:16:55

Generated On: 09 Jun 2021 16:25:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:16:55

Generated On: 09 Jun 2021 16:25:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	14:03 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 14:03
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:16:55

Generated On: 09 Jun 2021 16:25:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3272085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:16:55

Generated On: 09 Jun 2021 16:25:43

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

Collection date (dd MMM yyyy)	2 OCT 2020
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Collection time (00:00-23:59)	14:14 (24 HR)
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Collection date and time (derived)	2 OCT 2020 14:14
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US3272085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:16:55

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	07 OCT 2020 00:02:56
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 OCT 2020 09:29:39
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 OCT 2020 02:38:31
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

04 NOV 2020 00:07:35

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 10:03:02
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 106
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"/>

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	25 NOV 2020 14:06:49
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 02:58:06

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 02:28:59

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

17 DEC 2020 12:56:04

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

20 DEC 2020 03:06:42

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 02:07:45

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 152

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

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

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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	10 JAN 2021 18:38:10
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 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	17 JAN 2021 02:31:27
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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	24 JAN 2021 10:51:42
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

31 JAN 2021 02:23:56

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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	07 FEB 2021 01:51:56
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 10:44:28
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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	21 FEB 2021 03:59:18
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

28 FEB 2021 02:30:27

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

07 MAR 2021 00:02:55

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

16 MAR 2021 12:50:34

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

24 MAR 2021 19:59:47

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 03:50:25

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

04 APR 2021 11:12:42

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 APR 2021 21:27:35
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Date and time of submission

02 MAY 2021 02:57:40

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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°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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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°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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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°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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 425

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

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

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

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

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

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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="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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	28 OCT 2021 23:59
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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 530

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

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

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

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

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

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

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

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03 FEB 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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°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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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°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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

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28 JUL 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Patient Cloud Open Date & Time	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 <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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

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01 SEP 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

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15 SEP 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

[Patient Cloud Open Date & Time](#)

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22 SEP 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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"/>

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3272085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:25:43

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 02:30:11

US3272085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3272085

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272085

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3272085

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272085

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:16:55

Generated On: 09 Jun 2021 16:25:43

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

Visit date (dd MMM yyyy)	15 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:16:55

Generated On: 09 Jun 2021 16:25:43

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) _____

US3272085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:16:55

Generated On: 09 Jun 2021 16:25:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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

US3272085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:16:55

Generated On: 09 Jun 2021 16:25:43

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

Collection date (dd MMM yyyy)	15 MAR 2021
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Collection time (00:00-23:59)	14:28 (24 HR)
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Collection date and time (derived)	15 MAR 2021 14:28
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US3272085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:16:55

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3272085

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted?

Yes ☒

No ☐

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

29 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272085

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272085

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:25:43

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"/>

US3272085

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:25:43

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3272085

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

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

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

Visit date (dd MMM yyyy)	19 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3272085

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

Date of updated informed consent (dd MMM yyyy)	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <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 (dd MMM yyyy)	19 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

US3272085

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

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

US3272085

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

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)	19 JAN 2021
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 14:36
Temperature (xxx.x)	36.7 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)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3272085

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

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)	19 JAN 2021
Time of assessment (00:00-23:59)	16:25 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 16:25
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3272085

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

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3272085

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

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 15:49 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 15:49

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

US3272085

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

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

Collection date (dd MMM yyyy)	19 JAN 2021
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Collection time (00:00-23:59)	14:19 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	19 JAN 2021 14:19
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US3272085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

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

Collection date (dd MMM yyyy)	19 JAN 2021
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Collection time (00:00 - 23:59)	14:21
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Collection Date and Time (derived)	19 JAN 2021 14:21
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US3272085

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

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

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

Visit date (dd MMM yyyy)	16 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

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)	16:11 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 16:11
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 FEB 2021
Time of assessment (00:00-23:59)	17:14 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 17:14
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3272085

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

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.

US3272085

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

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) 16:37 (24 HR)

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

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

US3272085

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 17:14:57

Generated On: 09 Jun 2021 16:25:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272085

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

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
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US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 MAR 2021
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 14:06
Temperature (xxx.x)	36.5 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)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272085

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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

US3272085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 17:14:56

Generated On: 09 Jun 2021 16:25:43

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

Collection date (dd MMM yyyy)	15 MAR 2021
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Collection time (00:00-23:59)	14:28 (24 HR)
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Collection date and time (derived)	15 MAR 2021 14:28
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US3272085

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 27 Nov 2020 16:27:42

Generated On: 09 Jun 2021 16:25:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:59:21

Generated On: 09 Jun 2021 16:25:43

AEID	USA-US070-2020-MRNA-1273-P30 1000006
Adverse event	WORSENING INTERMITTENT CHEST WALL PAIN NON CARDIAC
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)	07 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	9 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	10 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:59:21

Generated On: 09 Jun 2021 16:25:43

	Unknown	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
<hr/>		
Other action taken (check all that apply)		
None		False
Concomitant Medication		True
Concomitant Procedure		False
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input checked="" type="radio"/>
	Recovered/Resolved with Sequelae	<input type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		
<hr/>		

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:59:21

Generated On: 09 Jun 2021 16:25:43

STATES ON 14OCT2020 THAT HE
STARTED WITH MILD CHEST
PAIN ON WEDNESDAY
07OCT2020 HE WOKE UP WITH
MILD CHEST PAIN,
DIAPHORESIS, AND SOME
NAUSEA. HE STATES BY
FRIDAY, 09OCT2020 THE CHEST
PAIN WAS WORSENING AND HE
WENT TO THE ER. HE WAS
THEN ADMITTED TO THE
HOSPITAL FOR A 24 HOUR
OBSERVATION TO R/O ACUTE
CORONARY SYNDROME, AND
PERICARDITIS. DIAGNOSIS
FROM HOSPITAL WAS CHEST
WALL PAIN. HE STATES
CARDIAC ENZYMES WERE
NORMAL AND HE WAS
DISCHARGED FROM THE
HOSPITAL ON 10OCT2020. HE
THEN SAW HIS PCP ON
14OCT2020 DUE TO CONTINUED
CHEST PAIN. PCP STATES THIS
IS INTERMITTENT CHEST WALL
PAIN THAT IS WORSENING AND
PATIENT WAS GIVEN A SCRIPT
FOR HYDROCODONE/APAP
5/325 MG AND CHOLCHICINE
0.6MG.

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

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 16:59:21

Generated On: 09 Jun 2021 16:25:43

AEID	
Adverse event	COUGH
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)	05 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)	13 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 16:59:21

Generated On: 09 Jun 2021 16:25:43

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3272085

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 16:59:21

Generated On: 09 Jun 2021 16:25:43

AEID

Adverse event

LACTIC ACIDOSIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

31 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 16:59:21

Generated On: 09 Jun 2021 16:25:43

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 16:59:21

Generated On: 09 Jun 2021 16:25:43

PARTICIPANT HAD ACCOMPANIED HIS WIFE TO THE ED FOR A MEDICAL EVENT FOR HER WHEN HE HAD A SYNCOPAL EPISODE AND WAS ADMITTED 31DEC2020. HE WAS WORKED UP FOR SEPSIS, HAD NEGATIVE PROCALCITONIN AND X-RAY. LABS WERE DRAWN AND HE WAS DIAGNOSED WITH LACTIC ACIDOSIS. HE WAS GIVEN CEFEPIME 1 GRAM Q6 FOR A POTENTIAL DIAGNOSIS OF SEPSIS WHICH WAS EVENTUALLY RULED OUT AND THE ANTIBIOTICS WERE DISCONTINUED. HE WAS REFERRED TO NEUROLOGY AND STARTED ON LEVETIRACETAM 500 MG PO BID FOR POTENTIAL SEIZURE ACTIVITY.

HE PRESENTED TO HIS PCP FOR FOLLOW-UP WHERE IT WAS SUSPECTED THAT HIS METFORMIN MAY HAVE INDUCED THE LACTIC ACIDOSIS AND WAS DISCONTINUED. HE REPORTED THE INCIDENT 06DEC2021.

LACTIC ACID:
01JAN2021: 4.6 AT 0543, 3.5 AT

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 16:59:21

Generated On: 09 Jun 2021 16:25:43

0800, 0.9 AT 1246.
02JAN2021: 1.7
PROCALCITONIN: <0.5
UA- TRACE PROTEIN,
GLUCOSE, RARE MUCOUS. NO
CULTURE INDICATED. CXR
NEGATIVE.
01JAN2021: INFLUENZA A, B,
RSV, COVID1-9 NEGATIVE.
BLOOD CULTURES AT DAY 2
AND 5 NEGATIVE.

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 16:59:21

Generated On: 09 Jun 2021 16:25:43

AEID	USA-US070-2021-MRNA-1273-P30 1000011
Adverse event	SYNCOPE
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)	31 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	02 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 16:59:21

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 14:53:31

Generated On: 09 Jun 2021 16:25:43

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

Yes ☒

No ☐

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

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	06 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 15

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 (2)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication LOSARTAN

Prophylaxis Yes ☒
No ☐

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication PIOGLITAZONE

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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 (5)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

	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 2012	
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)	2	
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) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☒
No ☐

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication LOW DOSE ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

	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 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication BYSTOLIC

Prophylaxis Yes ☒
No ☐

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication COLESTIPOL

Prophylaxis Yes ☐
No ☒

Indication DIARRHEA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication HYDROCODONE/APAP

Prophylaxis Yes ☐
No ☒

Indication WORSENING INTERMITTENT
CHEST WALL PAIN

Dose per administration 5/325

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

If dose unit is Other, specify 1-2 TABLETS MAX 10/650MG

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

If frequency is Other, specify EVERY 4-6 AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication CHOLCHICINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING INTERMITTENT
CHEST WALL PAIN

Dose per administration 0.6

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication LEVETIRACETAM

Prophylaxis Yes ☐
No ☒

Indication SYNCOPE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

Name of Medication CEFEPIME

Prophylaxis Yes ☐
No ☒

Indication LACTIC ACIDOSIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	01 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 14:53:32

Generated On: 09 Jun 2021 16:25:43

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) 29 Apr 2021 22:15:27

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 JAN 2021	ELECTROENCEPHALOGRAM	Adverse Event	
31 DEC 2020	WORK UP FOR SEPSIS	Adverse Event	
31 DEC 2020	NEGATIVE PROCALCITONIN	Adverse Event	
31 DEC 2020	X-RAY	Adverse Event	
04 JAN 2021	ELECTROENCEPHALOGRAM	Adverse Event	
01 JAN 2021	EKG	Adverse Event	
02 JAN 2021	MRI	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:25:43

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

US3272085

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:25:43

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 ☐

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	15/OCT/2020 20:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	29/OCT/2020 16:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	03/NOV/2020 14:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	20/NOV/2020 15:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	02/DEC/2020 18:03
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

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	04/JAN/2021 10:07
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

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/APR/2021 11:47
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

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	29/APR/2021 16:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Data signed: (b) (4) 03 May 2021 16:59:22

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US070-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	30/APR/2021 13:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 22:15:27

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US070-2021-MRNA-1273-P301000011
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 22:15:27

Generated On: 09 Jun 2021 16:25:43

SAEID	USA-US070-2021-MRNA-1273-P301000011
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	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	29/APR/2021 13:58
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

US3272085 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272085

Form: Participant Creation

Generated On: 09 Jun 2021 16:25:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 16:11:43
User entered 'US3272085'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:09:16

US3272085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:13:37

US3272085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:09:17

US3272085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Aug 2020 22:13:37

US3272085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'SCRN'	System	07 Aug 2020 22:13:37

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered (b) (6)1961'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:09:17

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Aug 2020 15:41:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 15:41:42
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	15 Aug 2020 15:41:42
User entered '58' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Aug 2020 15:41:42
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 22:13:58
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	07 Aug 2020 22:13:58
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'YEARS'	System	15 Aug 2020 15:41:42
User entered empty.	System	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '58'	System	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Male (M)'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'I'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:25:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 22:13:58

US3272085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Aug 2020'	System	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2020'	System	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 22:14:33

US3272085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:09:17

US3272085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:25:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '1'	System	07 Aug 2020 22:14:43

US3272085

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:14:43

US3272085

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:25:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 13:02:36

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 12:49:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 12:49:37
	(b) (4)	
Data point term sent to Coder	System	10 Aug 2020 13:17:26
User entered 'Penicillin Allergy/ anaphylaxis'	(b) (4), (b) (6)	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'un UNK 1970'	(b) (4), (b) (6)	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Jan 1970'	System	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '1970'	System	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	10 Aug 2020 13:17:09

US3272085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:49:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:49:18
Data point term sent to Coder	System	11 Aug 2020 13:48:14
User entered 'type 2 diabetes'	(b) (4), (b) (6)	11 Aug 2020 13:48:08

US3272085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'UN UNK 2007'	(b) (4), (b) (6)	11 Aug 2020 13:48:08

US3272085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:48:08

US3272085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:48:08

US3272085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:48:08

US3272085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:48:08

US3272085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Jan 2007'	System	11 Aug 2020 13:48:08

US3272085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2007'	System	11 Aug 2020 13:48:08

US3272085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	11 Aug 2020 13:48:08

US3272085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	11 Aug 2020 13:48:08

US3272085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 22:53:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 22:53:35
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 22:53:00
Coding entries removed.	(b) (4), (b) (6)	13 Nov 2020 22:52:14
User entered 'osteoARTHRITIS' reason for change: Data Entry Error		13 Nov 2020 22:52:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Polyarthritis, LLT: Generalized arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:50:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:50:13
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 13:49:17
User entered 'generalized arthritis'	(b) (4), (b) (6)	11 Aug 2020 13:48:37

US3272085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'UN UNK 2010'	(b) (4), (b) (6)	11 Aug 2020 13:48:37

US3272085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:48:37

US3272085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:48:37

US3272085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:48:37

US3272085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:48:37

US3272085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Jan 2010'	System	11 Aug 2020 13:48:37

US3272085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2010'	System	11 Aug 2020 13:48:37

US3272085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	11 Aug 2020 13:48:37

US3272085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	11 Aug 2020 13:48:37

US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:50:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:50:13
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 13:49:17
User entered 'hypertension'	(b) (4), (b) (6)	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'UN UNK 2010'	(b) (4), (b) (6)	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Jan 2010'	System	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2010'	System	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	11 Aug 2020 13:48:53

US3272085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
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)	11 Aug 2020 13:51:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:51:17
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 13:50:18
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	11 Aug 2020 13:49:20

US3272085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'UN UNK 2012'	(b) (4), (b) (6)	11 Aug 2020 13:49:20

US3272085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:49:20

US3272085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:49:20

US3272085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:49:20

US3272085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:49:20

US3272085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Jan 2012'	System	11 Aug 2020 13:49:20

US3272085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2012'	System	11 Aug 2020 13:49:20

US3272085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	11 Aug 2020 13:49:20

US3272085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	11 Aug 2020 13:49:20

US3272085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Cardiac disorders, HLGT: Pericardial disorders, HLT: Noninfectious pericarditis, PT: Pericarditis, LLT: Pericarditis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:51:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:51:17
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 13:50:21
User entered 'pericarditis'	(b) (4), (b) (6)	11 Aug 2020 13:50:11

US3272085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'UN Jun 2019'	(b) (4), (b) (6)	11 Aug 2020 13:50:11

US3272085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:50:11

US3272085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:50:11

US3272085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'UN Jul 2019'	(b) (4), (b) (6)	11 Aug 2020 13:50:11

US3272085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:50:11

US3272085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Jun 2019'	System	11 Aug 2020 13:50:11

US3272085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2019'	System	11 Aug 2020 13:50:11

US3272085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Jul 2019'	System	11 Aug 2020 13:50:11

US3272085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2019'	System	11 Aug 2020 13:50:11

US3272085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:52:09
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:52:09
Data point term sent to Coder	System	11 Aug 2020 13:51:24
User entered 'gastroesophageal reflux disease'	(b) (4), (b) (6)	11 Aug 2020 13:50:48

US3272085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'UN UNK 2009'	(b) (4), (b) (6)	11 Aug 2020 13:50:48

US3272085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:50:48

US3272085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:50:48

US3272085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:50:48

US3272085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:50:48

US3272085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Jan 2009'	System	11 Aug 2020 13:50:48

US3272085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2009'	System	11 Aug 2020 13:50:48

US3272085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	11 Aug 2020 13:50:48

US3272085

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	11 Aug 2020 13:50:48

US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Product issues, HLGT: Device issues, HLT: Device malfunction events NEC, PT: Device occlusion, LLT: Device occlusion - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 10:15:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 10:15:22
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 13:52:24
User entered 'amplatzer cribriform occluder device'	(b) (4), (b) (6)	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '29 May 2013'	(b) (4), (b) (6)	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: Ongoing is marked for a procedure. Please review and confirm to add a stop date as procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:09:06
Query 'Per DM CLR: Ongoing is marked for a procedure. Please review and confirm to add a stop date as procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'data correct' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 20:27:23
User opened query 'Per DM CLR: Ongoing is marked for a procedure. Please review and confirm to add a stop date as procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:06:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'May 2013'	System	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2013'	System	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	11 Aug 2020 13:51:46

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Congenital, familial and genetic disorders, HLG: Cardiac and vascular disorders congenital, HLT: Cardiac septal defects congenital, PT: Atrial septal defect, LLT: Foramen ovale patent - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 13:54:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 13:54:17
Data point term sent to Coder	System	11 Aug 2020 13:53:26
User entered 'patent foramen ovale'	(b) (4), (b) (6)	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'UN UNK 2011'	(b) (4), (b) (6)	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '29 May 2013'	(b) (4), (b) (6)	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Jan 2011'	System	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2011'	System	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'May 2013'	System	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2013'	System	11 Aug 2020 13:52:58

US3272085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: Transient ischemic attacks - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:55:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 13:55:20
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 13:54:28
User entered 'transient ischemic attacks'	(b) (4), (b) (6)	11 Aug 2020 13:54:01

US3272085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'UN UNK 2007'	(b) (4), (b) (6)	11 Aug 2020 13:54:01

US3272085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:54:01

US3272085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:54:01

US3272085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '29 May 2013'	(b) (4), (b) (6)	11 Aug 2020 13:54:01

US3272085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:54:01

US3272085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Jan 2007'	System	11 Aug 2020 13:54:01

US3272085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2007'	System	11 Aug 2020 13:54:01

US3272085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'May 2013'	System	11 Aug 2020 13:54:01

US3272085

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2013'	System	11 Aug 2020 13:54:01

US3272085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Chest wall pain - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:22:25
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:22:25
	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 16:04:15
User entered 'Intermittent chest wall pain'	Ashley Bell (b) (4)	15 Oct 2020 16:03:20

US3272085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'un Dec 2019'	Ashley Bell (b) (4)	15 Oct 2020 16:03:20

US3272085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Oct 2020 16:03:20

US3272085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	Ashley Bell (b) (4)	15 Oct 2020 16:03:20

US3272085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:03:20

US3272085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Oct 2020 16:03:20

US3272085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Dec 2019'	System	15 Oct 2020 16:03:20

US3272085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2019'	System	15 Oct 2020 16:03:20

US3272085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	15 Oct 2020 16:03:20

US3272085

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	15 Oct 2020 16:03:20

US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:10:15
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:10:15
	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 16:08:22
User entered 'Diarrhea'	Ashley Bell (b) (4)	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'un UNK 2015'	Ashley Bell (b) (4)	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	Ashley Bell (b) (4)	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'Jan 2015'	System	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '2015'	System	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered empty.	System	15 Oct 2020 16:07:22

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:16:22
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'UPDATED' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 18:15:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:17:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered 'Yes (Y)'		11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '07 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '7 Aug 2020'		11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '15:30' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '15:30'	(b) (4), (b) (6)	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '07 Aug 2020 15:30'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered '7 Aug 2020 15:30'	System	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '179' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '179' cm		11 Aug 2020 13:55:24
DataPoint set to visible.	System	07 Aug 2020 22:14:43

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '89.4' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '89.4' kg	(b) (4), (b) (6)	11 Aug 2020 13:55:24
DataPoint set to visible.	System	07 Aug 2020 22:14:43

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered '27.90175'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered '27.9'	System	11 Aug 2020 13:55:24
DataPoint set to visible.	System	07 Aug 2020 22:14:43

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'kg/m2'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered 'kg/m2'	System	11 Aug 2020 13:55:24
DataPoint set to visible.	System	07 Aug 2020 22:14:43

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:12:22
Query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' answered with 'UPDATED' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 18:15:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User opened query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:17:25
User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:17:25
Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 23:56:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 20:48:19

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37' C	(b) (4), (b) (6)	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered 'Other (Other)'		11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered 'temporal'		11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '67'		11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'bpm'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered 'bpm'	System	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '24'		11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'breaths/min'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered 'breaths/min'	System	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '117'		11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'mmHg'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered 'mmHg'	System	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 18:15:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:56:39
User entered '72'		11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User entered 'mmHg'	System	25 Sep 2020 18:15:40
User entered empty.	System	15 Sep 2020 23:56:39
User entered 'mmHg'	System	11 Aug 2020 13:55:24

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26

US3272085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26

US3272085

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:55:31

US3272085

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:37:47
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		05 Sep 2020 02:15:46
User entered '7 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 13:55:31

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:56:06

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:25:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:44:26
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 13:56:06

US3272085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:15:28

US3272085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 22:15:28

US3272085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[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 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Aug 2020 22:15:28

US3272085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'VISIT1'	System	07 Aug 2020 22:15:28

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:19:33

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:01:31
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:01:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 21:19:33
User entered '143222' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:19:33

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:19:33

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

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 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:25:36

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

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 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:25:36

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:25:36

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:25:36

US3272085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:25:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:25:36

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:41:59
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:28:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:28:10
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 16:27:59
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:42:02
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:28:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:28:10
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 16:28:12
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:41:59
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).		02 Sep 2020 22:28:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:28:10
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 16:27:59
User entered empty.		10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:42:02
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:28:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:28:10
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 16:28:12
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User accepted default value 'Pre-Dose (PREDOSE)'		10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '15:30'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered '07 Aug 2020 15:30'	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '37.0' C	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Other (Other)'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'TEMPORAL'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '67' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'bpm'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '24' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'breaths/min'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '117' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'mmHg'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'mmHg'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:41:59
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:28:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:28:10
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).		28 Aug 2020 16:27:59
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 19:42:02
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 22:28:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 22:28:10
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 16:28:12
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User accepted default value 'Post-Dose (POSTDOSE)'		10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 10:39:20
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 12:28:18
User entered '17:27'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered '07 Aug 2020 17:27'	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '36.6' C	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Other (Other)'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'TEMPORAL'	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'bpm'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'breaths/min'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '120' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'mmHg'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 22:47:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Aug 2020 22:47:53
User entered '79' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 22:47:53
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 12:28:18
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'mmHg'	System	18 Aug 2020 22:47:53
User entered empty.	System	10 Aug 2020 12:28:18

US3272085

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:28:56

US3272085

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 12:28:56

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	07 Aug 2020 22:16:50
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	07 Aug 2020 22:16:50
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	07 Aug 2020 22:16:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '16:51'	(b) (4), (b) (6)	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered '07 Aug 2020 16:51'	System	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Left Arm (LEFT ARM)' reason for change: New Information	(b) (4), (b) (6)	07 Aug 2020 22:16:50
User entered empty.		07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'ONCE'	System	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 22:16:40

US3272085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:34:51

US3272085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '07 Aug 2020'	(b) (4), (b) (6)	10 Aug 2020 12:34:51

US3272085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '15:50' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:03:31
User entered '16:51'	(b) (4), (b) (6)	10 Aug 2020 12:34:51

US3272085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered '07 Aug 2020 15:50'	System	13 Nov 2020 23:03:31
User entered '07 Aug 2020 16:51'	System	10 Aug 2020 12:34:51

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:25:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User closed query 'Per CDM: Per CCGs data is required. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 18:10:02
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 18:10:00
Query 'Per CDM: Per CCGs data is required. Please review and update accordingly' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 23:29:19
User entered '7 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 23:29:01
User opened query 'Per CDM: Per CCGs data is required. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 12:35:42
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered with '30 MIN SIT TIME PER PROTOCOL ' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 12:38:07
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	10 Aug 2020 12:36:42
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '15:47' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:03:43
User entered '15:50'		10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered '7 Aug 2020 15:47'	System	13 Nov 2020 23:03:43
User entered '7 Aug 2020 15:50'	System	16 Sep 2020 23:29:01
User entered empty.	System	10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 12:36:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 12:36:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 12:36:49
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 12:36:42
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered empty.	System	10 Aug 2020 12:36:42

US3272085

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:38:15

US3272085

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:25:24
User entered 'I'	System	10 Aug 2020 12:38:15

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:25:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '15963001-991b-4039-ae19-a68c065b95fa'	System	07 Aug 2020 22:25:48
User entered 'Yes (Y)'	System	07 Aug 2020 22:25:48

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:25:36', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '15963001-991b-4039-ae19-a68c065b95fa'	System	07 Aug 2020 22:25:48
User entered '98.4'	System	07 Aug 2020 22:25:48

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:25:41', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '15963001-991b-4039-ae19-a68c065b95fa'	System	07 Aug 2020 22:25:48
User entered 'No (N)'	System	07 Aug 2020 22:25:48

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:25:46', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '15963001-991b-4039-ae19-a68c065b95fa'	System	07 Aug 2020 22:25:48
User entered '07 Aug 2020 17:25'	System	07 Aug 2020 22:25:48

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Aug 2020 17:11'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Aug 2020 19:41'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:08:43', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4e4c3e46-3497-49a5-aec2-e26a0ea5847f'	System	08 Aug 2020 04:09:00
User entered 'Yes (Y)'	System	08 Aug 2020 04:09:00

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:08:49', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4e4c3e46-3497-49a5-aec2-e26a0ea5847f' User entered '97.5'	System	08 Aug 2020 04:09:00
	System	08 Aug 2020 04:09:00

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:08:54', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4e4c3e46-3497-49a5-aec2-e26a0ea5847f'	System	08 Aug 2020 04:09:00
User entered 'No (N)'	System	08 Aug 2020 04:09:00

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:08:58', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4e4c3e46-3497-49a5-aec2-e26a0ea5847f'	System	08 Aug 2020 04:09:00
User entered '07 Aug 2020 23:08'	System	08 Aug 2020 04:09:00

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Aug 2020 20:36'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 2'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:25', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'af075266-2b33-4d63-80bd-aa144e8a5c5b'	System	09 Aug 2020 01:58:40
User entered 'Yes (Y)'	System	09 Aug 2020 01:58:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'af075266-2b33-4d63-80bd-aa144e8a5c5b'	System	09 Aug 2020 01:58:40
User entered '97.6'	System	09 Aug 2020 01:58:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'af075266-2b33-4d63-80bd-aa144e8a5c5b'	System	09 Aug 2020 01:58:40
User entered 'No (N)'	System	09 Aug 2020 01:58:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'af075266-2b33-4d63-80bd-aa144e8a5c5b'	System	09 Aug 2020 01:58:40
User entered '08 Aug 2020 20:58'	System	09 Aug 2020 01:58:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 3'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '16877a62-8222-4b14-8ab8-277cbda86d9'	System	09 Aug 2020 22:31:28
User entered 'Yes (Y)'	System	09 Aug 2020 22:31:28

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:18', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '16877a62-8222-4b14-8ab8-277cbda86d9' User entered '97.9'	System	09 Aug 2020 22:31:28
	System	09 Aug 2020 22:31:28

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:21', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '16877a62-8222-4b14-8ab8-277cbda86d9'	System	09 Aug 2020 22:31:28
User entered 'No (N)'	System	09 Aug 2020 22:31:28

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:26', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '16877a62-8222-4b14-8ab8-277cbda86d9'	System	09 Aug 2020 22:31:28
User entered '09 Aug 2020 17:31'	System	09 Aug 2020 22:31:28

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 4'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:16', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fb249ca0-f5c4-4020-bb23-9a030caefb5e'	System	11 Aug 2020 03:11:31
User entered 'Yes (Y)'	System	11 Aug 2020 03:11:31

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:21', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fb249ca0-f5c4-4020-bb23-9a030caefb5e'	System	11 Aug 2020 03:11:31
User entered '97.5'	System	11 Aug 2020 03:11:31

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fb249ca0-f5c4-4020-bb23-9a030caefb5e'	System	11 Aug 2020 03:11:31
User entered 'No (N)'	System	11 Aug 2020 03:11:31

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:27', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fb249ca0-f5c4-4020-bb23-9a030caefb5e'	System	11 Aug 2020 03:11:31
User entered '10 Aug 2020 22:11'	System	11 Aug 2020 03:11:31

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 5'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:09:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b396062a-ed72-4f83-9b86-272d58fcbde3'	System	12 Aug 2020 03:09:59
User entered 'Yes (Y)'	System	12 Aug 2020 03:09:59

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:09:48', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b396062a-ed72-4f83-9b86-272d58fcbde3'	System	12 Aug 2020 03:09:59
User entered '97.6'	System	12 Aug 2020 03:09:59

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:09:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b396062a-ed72-4f83-9b86-272d58fcbde3'	System	12 Aug 2020 03:09:59
User entered 'No (N)'	System	12 Aug 2020 03:09:59

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:09:55', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b396062a-ed72-4f83-9b86-272d58fcbde3'	System	12 Aug 2020 03:09:59
User entered '11 Aug 2020 21:09'	System	12 Aug 2020 03:09:59

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 6'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:27:31', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '42c96675-3505-4d4e-ac7f-54bed42d9b26'	System	13 Aug 2020 03:27:47
User entered 'No (N)'	System	13 Aug 2020 03:27:47

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:27:35', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '42c96675-3505-4d4e-ac7f-54bed42d9b26'	System	13 Aug 2020 03:27:47
User entered 'No (N)'	System	13 Aug 2020 03:27:47

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:27:44', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '42c96675-3505-4d4e-ac7f-54bed42d9b26'	System	13 Aug 2020 03:27:47
User entered '12 Aug 2020 22:27'	System	13 Aug 2020 03:27:47

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 7'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:01:58', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '9462ab27-75a7-4f08-949c-9c78da8d5d5c'	System	14 Aug 2020 02:02:14
User entered 'Yes (Y)'	System	14 Aug 2020 02:02:14

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '9462ab27-75a7-4f08-949c-9c78da8d5d5c'	System	14 Aug 2020 02:02:14
User entered '97.8'	System	14 Aug 2020 02:02:14

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:08', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '9462ab27-75a7-4f08-949c-9c78da8d5d5c'	System	14 Aug 2020 02:02:14
User entered 'No (N)'	System	14 Aug 2020 02:02:14

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '9462ab27-75a7-4f08-949c-9c78da8d5d5c'	System	14 Aug 2020 02:02:14
User entered '13 Aug 2020 21:02'	System	14 Aug 2020 02:02:14

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:34:22', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'baa18a7d-a0a9-4e48-9fc1-3fa2f51583b1'	System	07 Aug 2020 22:35:01
User entered 'None (1)'	System	07 Aug 2020 22:35:01

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:34:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'baa18a7d-a0a9-4e48-9fc1-3fa2f51583b1'	System	07 Aug 2020 22:35:01
User entered 'No (N)'	System	07 Aug 2020 22:35:01

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:34:41', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'baa18a7d-a0a9-4e48-9fc1-3fa2f51583b1'	System	07 Aug 2020 22:35:01
User entered 'No (N)'	System	07 Aug 2020 22:35:01

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:34:48', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'baa18a7d-a0a9-4e48-9fc1-3fa2f51583b1'	System	07 Aug 2020 22:35:01
User entered 'None (1)'	System	07 Aug 2020 22:35:01

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:34:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'baa18a7d-a0a9-4e48-9fc1-3fa2f51583b1'	System	07 Aug 2020 22:35:01
User entered '07 Aug 2020 17:34'	System	07 Aug 2020 22:35:01

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Aug 2020 17:11'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Aug 2020 19:41'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:06', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '399b97d9-0310-462a-968c-221bc0c5e0af'	System	08 Aug 2020 04:09:31
User entered 'None (1)'	System	08 Aug 2020 04:09:31

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '399b97d9-0310-462a-968c-221bc0c5e0af'	System	08 Aug 2020 04:09:31
User entered 'No (N)'	System	08 Aug 2020 04:09:31

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:13', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '399b97d9-0310-462a-968c-221bc0c5e0af'	System	08 Aug 2020 04:09:31
User entered 'No (N)'	System	08 Aug 2020 04:09:31

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:22', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '399b97d9-0310-462a-968c-221bc0c5e0af'	System	08 Aug 2020 04:09:31
User entered 'None (1)'	System	08 Aug 2020 04:09:31

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:26', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '399b97d9-0310-462a-968c-221bc0c5e0af'	System	08 Aug 2020 04:09:31
User entered '07 Aug 2020 23:09'	System	08 Aug 2020 04:09:31

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Aug 2020 20:36'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 2'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3410980a-2066-46a7-abb7-6c92ab7973a9'	System	09 Aug 2020 01:59:04
User entered 'None (1)'	System	09 Aug 2020 01:59:04

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3410980a-2066-46a7-abb7-6c92ab7973a9'	System	09 Aug 2020 01:59:04
User entered 'No (N)'	System	09 Aug 2020 01:59:04

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3410980a-2066-46a7-abb7-6c92ab7973a9'	System	09 Aug 2020 01:59:04
User entered 'No (N)'	System	09 Aug 2020 01:59:04

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:58:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3410980a-2066-46a7-abb7-6c92ab7973a9'	System	09 Aug 2020 01:59:04
User entered 'None (1)'	System	09 Aug 2020 01:59:04

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:02', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3410980a-2066-46a7-abb7-6c92ab7973a9'	System	09 Aug 2020 01:59:04
User entered '08 Aug 2020 20:59'	System	09 Aug 2020 01:59:04

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 3'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '964bfa99-b182-440f-9d60-73931be580db'	System	09 Aug 2020 22:31:45
User entered 'None (1)'	System	09 Aug 2020 22:31:45

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '964bfa99-b182-440f-9d60-73931be580db'	System	09 Aug 2020 22:31:45
User entered 'No (N)'	System	09 Aug 2020 22:31:45

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:36', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '964bfa99-b182-440f-9d60-73931be580db'	System	09 Aug 2020 22:31:45
User entered 'No (N)'	System	09 Aug 2020 22:31:45

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '964bfa99-b182-440f-9d60-73931be580db'	System	09 Aug 2020 22:31:45
User entered 'None (1)'	System	09 Aug 2020 22:31:45

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '964bfa99-b182-440f-9d60-73931be580db'	System	09 Aug 2020 22:31:45
User entered '09 Aug 2020 17:31'	System	09 Aug 2020 22:31:45

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 4'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2ffd53e8-ad44-4f7e-964f-80c5badd7761'	System	11 Aug 2020 03:12:10
User entered 'None (1)'	System	11 Aug 2020 03:12:10

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:36', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2ffd53e8-ad44-4f7e-964f-80c5badd7761'	System	11 Aug 2020 03:12:10
User entered 'No (N)'	System	11 Aug 2020 03:12:10

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:11:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2ffd53e8-ad44-4f7e-964f-80c5badd7761'	System	11 Aug 2020 03:12:10
User entered 'No (N)'	System	11 Aug 2020 03:12:10

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:03', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2ffd53e8-ad44-4f7e-964f-80c5badd7761'	System	11 Aug 2020 03:12:10
User entered 'None (1)'	System	11 Aug 2020 03:12:10

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:06', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2ffd53e8-ad44-4f7e-964f-80c5badd7761'	System	11 Aug 2020 03:12:10
User entered '10 Aug 2020 22:12'	System	11 Aug 2020 03:12:10

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 5'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:06', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '77c0acb7-1268-425d-88cb-9c35dc68c294'	System	12 Aug 2020 03:10:30
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 03:10:30

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '77c0acb7-1268-425d-88cb-9c35dc68c294'	System	12 Aug 2020 03:10:30
User entered 'No (N)'	System	12 Aug 2020 03:10:30

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:13', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '77c0acb7-1268-425d-88cb-9c35dc68c294'	System	12 Aug 2020 03:10:30
User entered 'No (N)'	System	12 Aug 2020 03:10:30

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '77c0acb7-1268-425d-88cb-9c35dc68c294'	System	12 Aug 2020 03:10:30
User entered 'None (1)'	System	12 Aug 2020 03:10:30

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:28', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '77c0acb7-1268-425d-88cb-9c35dc68c294'	System	12 Aug 2020 03:10:30
User entered '11 Aug 2020 21:10'	System	12 Aug 2020 03:10:30

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 6'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:28:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e75f55a7-9282-4946-b0ce-e8270f6c00ac'	System	13 Aug 2020 03:29:17
User entered 'None (1)'	System	13 Aug 2020 03:29:17

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:00', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e75f55a7-9282-4946-b0ce-e8270f6c00ac'	System	13 Aug 2020 03:29:17
User entered 'No (N)'	System	13 Aug 2020 03:29:17

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e75f55a7-9282-4946-b0ce-e8270f6c00ac'	System	13 Aug 2020 03:29:17
User entered 'No (N)'	System	13 Aug 2020 03:29:17

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:09', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e75f55a7-9282-4946-b0ce-e8270f6c00ac'	System	13 Aug 2020 03:29:17
User entered 'None (1)'	System	13 Aug 2020 03:29:17

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:14', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e75f55a7-9282-4946-b0ce-e8270f6c00ac'	System	13 Aug 2020 03:29:17
User entered '12 Aug 2020 22:29'	System	13 Aug 2020 03:29:17

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 7'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '41f15775-0bdc-44d2-b3b1-77bc0f28c416'	System	14 Aug 2020 02:02:37
User entered 'None (1)'	System	14 Aug 2020 02:02:37

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:20', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '41f15775-0bdc-44d2-b3b1-77bc0f28c416'	System	14 Aug 2020 02:02:37
User entered 'No (N)'	System	14 Aug 2020 02:02:37

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:22', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '41f15775-0bdc-44d2-b3b1-77bc0f28c416'	System	14 Aug 2020 02:02:37
User entered 'No (N)'	System	14 Aug 2020 02:02:37

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '41f15775-0bdc-44d2-b3b1-77bc0f28c416'	System	14 Aug 2020 02:02:37
User entered 'None (1)'	System	14 Aug 2020 02:02:37

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '41f15775-0bdc-44d2-b3b1-77bc0f28c416'	System	14 Aug 2020 02:02:37
User entered '13 Aug 2020 21:02'	System	14 Aug 2020 02:02:37

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'None (0)'	System	07 Aug 2020 22:36:01

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:16', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'None (0)'	System	07 Aug 2020 22:36:01

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:21', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'None (0)'	System	07 Aug 2020 22:36:01

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:32', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'None (0)'	System	07 Aug 2020 22:36:01

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'None (0)'	System	07 Aug 2020 22:36:01

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:43', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'None (0)'	System	07 Aug 2020 22:36:01

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:52', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered 'No (N)'	System	07 Aug 2020 22:36:01

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T17:35:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2f3341ab-025a-4e6f-8afe-8ae9e65d4b37'	System	07 Aug 2020 22:36:01
User entered '07 Aug 2020 17:35'	System	07 Aug 2020 22:36:01

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Aug 2020 17:11'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Aug 2020 19:41'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:32', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'None (0)'	System	08 Aug 2020 04:10:03

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:38', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'None (0)'	System	08 Aug 2020 04:10:03

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:41', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'None (0)'	System	08 Aug 2020 04:10:03

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:44', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'None (0)'	System	08 Aug 2020 04:10:03

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:46', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'None (0)'	System	08 Aug 2020 04:10:03

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'None (0)'	System	08 Aug 2020 04:10:03

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:54', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered 'No (N)'	System	08 Aug 2020 04:10:03

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-07T23:09:57', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '61625c11-9245-4f2b-8e9b-bc922e41e6e5'	System	08 Aug 2020 04:10:03
User entered '07 Aug 2020 23:09'	System	08 Aug 2020 04:10:03

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Aug 2020 20:36'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 2'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:09', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'None (0)'	System	09 Aug 2020 01:59:43

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'No interference with activity (1)'	System	09 Aug 2020 01:59:43

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'None (0)'	System	09 Aug 2020 01:59:43

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:27', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'No interference with activity (1)'	System	09 Aug 2020 01:59:43

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:29', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'None (0)'	System	09 Aug 2020 01:59:43

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:32', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'None (0)'	System	09 Aug 2020 01:59:43

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:36', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered 'No (N)'	System	09 Aug 2020 01:59:43

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-08T20:59:38', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edf225da-83bb-4662-81d1-b972f414d3d3'	System	09 Aug 2020 01:59:43
User entered '08 Aug 2020 20:59'	System	09 Aug 2020 01:59:43

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 3'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'None (0)'	System	09 Aug 2020 22:32:07

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:48', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'None (0)'	System	09 Aug 2020 22:32:07

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'None (0)'	System	09 Aug 2020 22:32:07

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:52', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'None (0)'	System	09 Aug 2020 22:32:07

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:55', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'None (0)'	System	09 Aug 2020 22:32:07

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:31:58', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'None (0)'	System	09 Aug 2020 22:32:07

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:32:02', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered 'No (N)'	System	09 Aug 2020 22:32:07

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-09T17:32:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4234b044-e717-49f3-914b-45e9a0fee3b7'	System	09 Aug 2020 22:32:07
User entered '09 Aug 2020 17:32'	System	09 Aug 2020 22:32:07

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 4'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'None (0)'	System	11 Aug 2020 03:12:54

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'None (0)'	System	11 Aug 2020 03:12:54

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:23', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'None (0)'	System	11 Aug 2020 03:12:54

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf' User entered 'None (0)'	System	11 Aug 2020 03:12:54
	System	11 Aug 2020 03:12:54

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:35', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'None (0)'	System	11 Aug 2020 03:12:54

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:38', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'None (0)'	System	11 Aug 2020 03:12:54

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered 'No (N)'	System	11 Aug 2020 03:12:54

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-10T22:12:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '68238193-de7e-4640-b0df-7ea7837700bf'	System	11 Aug 2020 03:12:54
User entered '10 Aug 2020 22:12'	System	11 Aug 2020 03:12:54

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 5'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'None (0)'	System	12 Aug 2020 03:11:13

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'None (0)'	System	12 Aug 2020 03:11:13

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'None (0)'	System	12 Aug 2020 03:11:13

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'No interference with activity (1)'	System	12 Aug 2020 03:11:13

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'None (0)'	System	12 Aug 2020 03:11:13

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:10:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'None (0)'	System	12 Aug 2020 03:11:13

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:11:07', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered 'No (N)'	System	12 Aug 2020 03:11:13

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-11T21:11:09', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '5bca7af8-6427-478c-9c16-80b60d0ad9e0'	System	12 Aug 2020 03:11:13
User entered '11 Aug 2020 21:11'	System	12 Aug 2020 03:11:13

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 6'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:26', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'None (0)'	System	13 Aug 2020 03:29:57

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'No interference with activity (1)'	System	13 Aug 2020 03:29:57

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'No interference with activity (1)'	System	13 Aug 2020 03:29:57

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:40', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'No interference with activity (1)'	System	13 Aug 2020 03:29:57

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:44', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'None (0)'	System	13 Aug 2020 03:29:57

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'None (0)'	System	13 Aug 2020 03:29:57

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered 'No (N)'	System	13 Aug 2020 03:29:57

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-12T22:29:55', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'febcd561-25fa-4e06-9430-25656c1af062'	System	13 Aug 2020 03:29:57
User entered '12 Aug 2020 22:29'	System	13 Aug 2020 03:29:57

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 7'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'None (0)'	System	14 Aug 2020 02:03:06

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:40', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'None (0)'	System	14 Aug 2020 02:03:06

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'None (0)'	System	14 Aug 2020 02:03:06

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'None (0)'	System	14 Aug 2020 02:03:06

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'None (0)'	System	14 Aug 2020 02:03:06

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'None (0)'	System	14 Aug 2020 02:03:06

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:02:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered 'No (N)'	System	14 Aug 2020 02:03:06

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-13T21:03:01', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7fceb181-76a0-44e5-a2b5-3acc2679b19f'	System	14 Aug 2020 02:03:06
User entered '13 Aug 2020 21:03'	System	14 Aug 2020 02:03:06

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	13 Aug 2020 03:29:57
User entered 'Day 8'	System	13 Aug 2020 03:29:57

US3272085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-15T00:02:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e033c075-60cf-4c5d-a26a-a46a9e31cbc8'	System	15 Aug 2020 05:02:22
User entered 'No (N)'	System	15 Aug 2020 05:02:22

US3272085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-08-15T00:02:18', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e033c075-60cf-4c5d-a26a-a46a9e31cbc8'	System	15 Aug 2020 05:02:22
User entered '15 Aug 2020 00:02'	System	15 Aug 2020 05:02:22

US3272085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 03:29:57

US3272085

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 03:29:57

US3272085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:45:59

US3272085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '15 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:45:59

US3272085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 21:45:59

US3272085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:45:59

US3272085

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:46:06

US3272085

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:49:33
User entered 'I'	System	28 Aug 2020 21:46:06

US3272085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:46:18

US3272085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '21 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:46:18

US3272085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 21:46:18

US3272085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:46:18

US3272085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:46:22

US3272085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:26
User entered 'I'	System	28 Aug 2020 21:46:22

US3272085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 21:44:33

US3272085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '28 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 21:44:33

US3272085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Sep 2020 21:44:33

US3272085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 21:44:33

US3272085

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 21:44:41

US3272085

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:38:07
User entered 'I'	System	01 Sep 2020 21:44:41

US3272085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	05 Sep 2020 02:15:46

US3272085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '04 Sep 2020'	Kayla Flege (b) (4)	05 Sep 2020 02:15:46

US3272085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[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 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4)	05 Sep 2020 02:15:46

US3272085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered 'VISIT2'	System	05 Sep 2020 02:15:46

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '04 Sep 2020'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '14:15' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:06:02
User entered '14:10'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18
	(b) (4)	

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered '04 Sep 2020 14:15'	System	13 Nov 2020 23:06:02
User entered '04 Sep 2020 14:10'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '36.7' C	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Oral (Oral)'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '73'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered 'bpm'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '16'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered 'breaths/min'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '123'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered 'mmHg'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '82'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered 'mmHg'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '4 Sep 2020'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '15:40'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered '4 Sep 2020 15:40'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '36.7' C	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Oral (Oral)'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '67'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered 'bpm'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '12'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered 'breaths/min'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '123'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered 'mmHg'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '85'	Kayla Flege (b) (4)	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered 'mmHg'	System	05 Sep 2020 02:17:18

US3272085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	05 Sep 2020 02:17:28

US3272085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '4 Sep 2020'	Kayla Flege (b) (4)	05 Sep 2020 02:17:28

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Kayla Flege (b) (4)	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Kayla Flege (b) (4)	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '04 Sep 2020'	Kayla Flege (b) (4)	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '15:09'	Kayla Flege (b) (4)	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered '04 Sep 2020 15:09'	System	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Left Arm (LEFT ARM)'	Kayla Flege (b) (4)	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered 'ONCE'	System	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 20:17:34

US3272085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	05 Sep 2020 02:17:50

US3272085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '4 Sep 2020'	Kayla Flege (b) (4)	05 Sep 2020 02:17:50

US3272085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '14:31'	Kayla Flege (b) (4)	05 Sep 2020 02:17:50

US3272085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered '4 Sep 2020 14:31'	System	05 Sep 2020 02:17:50

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:25:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '04 Sep 2020'	Kayla Flege (b) (4)	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '14:24'	Kayla Flege (b) (4)	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered '04 Sep 2020 14:24'	System	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'No (N)'	Kayla Flege (b) (4)	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Kayla Flege (b) (4)	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered empty.	System	05 Sep 2020 02:18:09

US3272085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	Kayla Flege (b) (4)	05 Sep 2020 02:18:14

US3272085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:44:18
User entered '1'	System	05 Sep 2020 02:18:14

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:07', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ec5359da-cee8-43a3-8167-bf06e59cc8a8'	System	04 Sep 2020 20:43:22
User entered 'Yes (Y)'	System	04 Sep 2020 20:43:22

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ec5359da-cee8-43a3-8167-bf06e59cc8a8'	System	04 Sep 2020 20:43:22
User entered '98.2'	System	04 Sep 2020 20:43:22

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:16', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ec5359da-cee8-43a3-8167-bf06e59cc8a8'	System	04 Sep 2020 20:43:22
User entered 'No (N)'	System	04 Sep 2020 20:43:22

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ec5359da-cee8-43a3-8167-bf06e59cc8a8'	System	04 Sep 2020 20:43:22
User entered '04 Sep 2020 15:43'	System	04 Sep 2020 20:43:22

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '04 Sep 2020 15:29'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '04 Sep 2020 17:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:03', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'a6a8f30f-317a-48e7-903d-26dde246f543'	System	05 Sep 2020 07:30:24
User entered 'Yes (Y)'	System	05 Sep 2020 07:30:24

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'a6a8f30f-317a-48e7-903d-26dde246f543'	System	05 Sep 2020 07:30:24
User entered '97.9'	System	05 Sep 2020 07:30:24

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'a6a8f30f-317a-48e7-903d-26dde246f543'	System	05 Sep 2020 07:30:24
User entered 'No (N)'	System	05 Sep 2020 07:30:24

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'a6a8f30f-317a-48e7-903d-26dde246f543'	System	05 Sep 2020 07:30:24
User entered '05 Sep 2020 02:30'	System	05 Sep 2020 07:30:24

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '04 Sep 2020 18:54'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 2'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fec4da26-6556-428e-bb9e-ee5d6776dfdb'	System	06 Sep 2020 02:19:27
User entered 'Yes (Y)'	System	06 Sep 2020 02:19:27

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:17', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fec4da26-6556-428e-bb9e-ee5d6776dfdb'	System	06 Sep 2020 02:19:27
User entered '97.9'	System	06 Sep 2020 02:19:27

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:20', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fec4da26-6556-428e-bb9e-ee5d6776dfdb'	System	06 Sep 2020 02:19:27
User entered 'No (N)'	System	06 Sep 2020 02:19:27

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:23', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fec4da26-6556-428e-bb9e-ee5d6776dfdb'	System	06 Sep 2020 02:19:27
User entered '05 Sep 2020 21:19'	System	06 Sep 2020 02:19:27

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 3'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:53:43', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e5908ffc-11a4-498e-a039-bb38caeb8a7a'	System	07 Sep 2020 02:53:57
User entered 'Yes (Y)'	System	07 Sep 2020 02:53:57

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:53:48', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e5908ffc-11a4-498e-a039-bb38caeb8a7a'	System	07 Sep 2020 02:53:57
User entered '98.1'	System	07 Sep 2020 02:53:57

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:53:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e5908ffc-11a4-498e-a039-bb38caeb8a7a'	System	07 Sep 2020 02:53:57
User entered 'No (N)'	System	07 Sep 2020 02:53:57

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:53:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'e5908ffc-11a4-498e-a039-bb38caeb8a7a'	System	07 Sep 2020 02:53:57
User entered '06 Sep 2020 21:53'	System	07 Sep 2020 02:53:57

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 4'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:02', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'bce719f7-831b-4908-872e-d9472e964c38'	System	08 Sep 2020 05:39:17
User entered 'Yes (Y)'	System	08 Sep 2020 05:39:17

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:08', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'bce719f7-831b-4908-872e-d9472e964c38'	System	08 Sep 2020 05:39:17
User entered '98.1'	System	08 Sep 2020 05:39:17

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'bce719f7-831b-4908-872e-d9472e964c38'	System	08 Sep 2020 05:39:17
User entered 'No (N)'	System	08 Sep 2020 05:39:17

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'bce719f7-831b-4908-872e-d9472e964c38'	System	08 Sep 2020 05:39:17
User entered '08 Sep 2020 00:39'	System	08 Sep 2020 05:39:17

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 5'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:25', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '373b149c-5c6e-4daf-8873-19d5392d58de'	System	09 Sep 2020 01:27:37
User entered 'Yes (Y)'	System	09 Sep 2020 01:27:37

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:29', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '373b149c-5c6e-4daf-8873-19d5392d58de' User entered '98.2'	System	09 Sep 2020 01:27:37
	System	09 Sep 2020 01:27:37

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:32', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '373b149c-5c6e-4daf-8873-19d5392d58de'	System	09 Sep 2020 01:27:37
User entered 'No (N)'	System	09 Sep 2020 01:27:37

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:34', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '373b149c-5c6e-4daf-8873-19d5392d58de' User entered '08 Sep 2020 20:27'	System	09 Sep 2020 01:27:37
	System	09 Sep 2020 01:27:37

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 6'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:25', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4f06efa2-0fea-424d-b549-10e24f381f30'	System	10 Sep 2020 05:00:37
User entered 'Yes (Y)'	System	10 Sep 2020 05:00:37

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4f06efa2-0fea-424d-b549-10e24f381f30'	System	10 Sep 2020 05:00:37
User entered '97.9'	System	10 Sep 2020 05:00:37

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:32', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4f06efa2-0fea-424d-b549-10e24f381f30'	System	10 Sep 2020 05:00:37
User entered 'No (N)'	System	10 Sep 2020 05:00:37

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:35', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4f06efa2-0fea-424d-b549-10e24f381f30'	System	10 Sep 2020 05:00:37
User entered '10 Sep 2020 00:00'	System	10 Sep 2020 05:00:37

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 7'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:01', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '1638072f-eb4b-4307-93a7-a1aca4dade68'	System	10 Sep 2020 23:35:12
User entered 'Yes (Y)'	System	10 Sep 2020 23:35:12

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:05', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '1638072f-eb4b-4307-93a7-a1aca4dade68'	System	10 Sep 2020 23:35:12
User entered '98.2'	System	10 Sep 2020 23:35:12

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:08', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '1638072f-eb4b-4307-93a7-a1aca4dade68'	System	10 Sep 2020 23:35:12
User entered 'No (N)'	System	10 Sep 2020 23:35:12

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '1638072f-eb4b-4307-93a7-a1aca4dade68'	System	10 Sep 2020 23:35:12
User entered '10 Sep 2020 18:35'	System	10 Sep 2020 23:35:12

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:40', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '324fba70-2194-463c-a46a-fb418b846a47'	System	04 Sep 2020 20:44:03
User entered 'None (1)'	System	04 Sep 2020 20:44:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:48', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '324fba70-2194-463c-a46a-fb418b846a47'	System	04 Sep 2020 20:44:03
User entered 'No (N)'	System	04 Sep 2020 20:44:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '324fba70-2194-463c-a46a-fb418b846a47'	System	04 Sep 2020 20:44:03
User entered 'No (N)'	System	04 Sep 2020 20:44:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '324fba70-2194-463c-a46a-fb418b846a47'	System	04 Sep 2020 20:44:03
User entered 'None (1)'	System	04 Sep 2020 20:44:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:43:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '324fba70-2194-463c-a46a-fb418b846a47'	System	04 Sep 2020 20:44:03
User entered '04 Sep 2020 15:43'	System	04 Sep 2020 20:44:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '04 Sep 2020 15:29'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '04 Sep 2020 17:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:26', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'aeaa8c59-9246-4f44-adff-9edab7e9d9c9'	System	05 Sep 2020 07:30:55
User entered 'None (1)'	System	05 Sep 2020 07:30:55

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:31', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'aeaa8c59-9246-4f44-adff-9edab7e9d9c9'	System	05 Sep 2020 07:30:55
User entered 'No (N)'	System	05 Sep 2020 07:30:55

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'aeaa8c59-9246-4f44-adff-9edab7e9d9c9'	System	05 Sep 2020 07:30:55
User entered 'No (N)'	System	05 Sep 2020 07:30:55

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'aeaa8c59-9246-4f44-adff-9edab7e9d9c9'	System	05 Sep 2020 07:30:55
User entered 'None (1)'	System	05 Sep 2020 07:30:55

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'aeaa8c59-9246-4f44-adff-9edab7e9d9c9'	System	05 Sep 2020 07:30:55
User entered '05 Sep 2020 02:30'	System	05 Sep 2020 07:30:55

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '04 Sep 2020 18:54'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 2'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '8aedc738-6c2e-40dc-a05c-243c24991edb'	System	06 Sep 2020 02:20:04
User entered 'None (1)'	System	06 Sep 2020 02:20:04

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '8aedc738-6c2e-40dc-a05c-243c24991edb'	System	06 Sep 2020 02:20:04
User entered 'No (N)'	System	06 Sep 2020 02:20:04

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '8aedc738-6c2e-40dc-a05c-243c24991edb'	System	06 Sep 2020 02:20:04
User entered 'No (N)'	System	06 Sep 2020 02:20:04

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '8aedc738-6c2e-40dc-a05c-243c24991edb'	System	06 Sep 2020 02:20:04
User entered 'None (1)'	System	06 Sep 2020 02:20:04

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:19:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '8aedc738-6c2e-40dc-a05c-243c24991edb'	System	06 Sep 2020 02:20:04
User entered '05 Sep 2020 21:19'	System	06 Sep 2020 02:20:04

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 3'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:53:57', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2275bbcf-824d-4ec7-b4f5-5232c2f6e66f'	System	07 Sep 2020 02:54:10
User entered 'None (1)'	System	07 Sep 2020 02:54:10

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:53:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2275bbcf-824d-4ec7-b4f5-5232c2f6e66f'	System	07 Sep 2020 02:54:10
User entered 'No (N)'	System	07 Sep 2020 02:54:10

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:02', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2275bbcf-824d-4ec7-b4f5-5232c2f6e66f'	System	07 Sep 2020 02:54:10
User entered 'No (N)'	System	07 Sep 2020 02:54:10

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2275bbcf-824d-4ec7-b4f5-5232c2f6e66f'	System	07 Sep 2020 02:54:10
User entered 'None (1)'	System	07 Sep 2020 02:54:10

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:06', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '2275bbcf-824d-4ec7-b4f5-5232c2f6e66f'	System	07 Sep 2020 02:54:10
User entered '06 Sep 2020 21:54'	System	07 Sep 2020 02:54:10

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 4'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:29', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edeb7092-cf96-4659-b6a6-3284bbcf5560'	System	08 Sep 2020 05:39:48
User entered 'None (1)'	System	08 Sep 2020 05:39:48

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edeb7092-cf96-4659-b6a6-3284bbcf5560'	System	08 Sep 2020 05:39:48
User entered 'No (N)'	System	08 Sep 2020 05:39:48

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edeb7092-cf96-4659-b6a6-3284bbcf5560'	System	08 Sep 2020 05:39:48
User entered 'No (N)'	System	08 Sep 2020 05:39:48

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edeb7092-cf96-4659-b6a6-3284bbcf5560'	System	08 Sep 2020 05:39:48
User entered 'None (1)'	System	08 Sep 2020 05:39:48

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'edeb7092-cf96-4659-b6a6-3284bbcf5560'	System	08 Sep 2020 05:39:48
User entered '08 Sep 2020 00:39'	System	08 Sep 2020 05:39:48

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 5'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd2b19296-4885-497f-b49b-0483bd53293d'	System	09 Sep 2020 01:28:03
User entered 'None (1)'	System	09 Sep 2020 01:28:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd2b19296-4885-497f-b49b-0483bd53293d'	System	09 Sep 2020 01:28:03
User entered 'No (N)'	System	09 Sep 2020 01:28:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd2b19296-4885-497f-b49b-0483bd53293d'	System	09 Sep 2020 01:28:03
User entered 'No (N)'	System	09 Sep 2020 01:28:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:57', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd2b19296-4885-497f-b49b-0483bd53293d'	System	09 Sep 2020 01:28:03
User entered 'None (1)'	System	09 Sep 2020 01:28:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:27:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd2b19296-4885-497f-b49b-0483bd53293d'	System	09 Sep 2020 01:28:03
User entered '08 Sep 2020 20:27'	System	09 Sep 2020 01:28:03

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 6'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd892a9e9-9dee-491e-9648-b981c2ce6554'	System	10 Sep 2020 05:00:56
User entered 'None (1)'	System	10 Sep 2020 05:00:56

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:41', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd892a9e9-9dee-491e-9648-b981c2ce6554'	System	10 Sep 2020 05:00:56
User entered 'No (N)'	System	10 Sep 2020 05:00:56

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:44', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd892a9e9-9dee-491e-9648-b981c2ce6554'	System	10 Sep 2020 05:00:56
User entered 'No (N)'	System	10 Sep 2020 05:00:56

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:49', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd892a9e9-9dee-491e-9648-b981c2ce6554'	System	10 Sep 2020 05:00:56
User entered 'None (1)'	System	10 Sep 2020 05:00:56

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'd892a9e9-9dee-491e-9648-b981c2ce6554'	System	10 Sep 2020 05:00:56
User entered '10 Sep 2020 00:00'	System	10 Sep 2020 05:00:56

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 7'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ba24bc20-7089-4533-9a0e-f377514da00c'	System	10 Sep 2020 23:35:36
User entered 'None (1)'	System	10 Sep 2020 23:35:36

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ba24bc20-7089-4533-9a0e-f377514da00c'	System	10 Sep 2020 23:35:36
User entered 'No (N)'	System	10 Sep 2020 23:35:36

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:27', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ba24bc20-7089-4533-9a0e-f377514da00c'	System	10 Sep 2020 23:35:36
User entered 'No (N)'	System	10 Sep 2020 23:35:36

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:31', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ba24bc20-7089-4533-9a0e-f377514da00c'	System	10 Sep 2020 23:35:36
User entered 'None (1)'	System	10 Sep 2020 23:35:36

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:34', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ba24bc20-7089-4533-9a0e-f377514da00c'	System	10 Sep 2020 23:35:36
User entered '10 Sep 2020 18:35'	System	10 Sep 2020 23:35:36

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:25', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'None (0)'	System	04 Sep 2020 20:44:45

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'None (0)'	System	04 Sep 2020 20:44:45

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:32', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'None (0)'	System	04 Sep 2020 20:44:45

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:34', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'None (0)'	System	04 Sep 2020 20:44:45

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:35', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'None (0)'	System	04 Sep 2020 20:44:45

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:37', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'None (0)'	System	04 Sep 2020 20:44:45

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:40', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered 'No (N)'	System	04 Sep 2020 20:44:45

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-04T15:44:43', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'fd80ac08-c6a6-467e-be2c-484e4bbe2a5b'	System	04 Sep 2020 20:44:45
User entered '04 Sep 2020 15:44'	System	04 Sep 2020 20:44:45

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '04 Sep 2020 15:29'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '04 Sep 2020 17:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:30:55', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'None (0)'	System	05 Sep 2020 07:31:26

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:00', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'None (0)'	System	05 Sep 2020 07:31:26

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'None (0)'	System	05 Sep 2020 07:31:26

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:08', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'None (0)'	System	05 Sep 2020 07:31:26

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'None (0)'	System	05 Sep 2020 07:31:26

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'None (0)'	System	05 Sep 2020 07:31:26

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered 'No (N)'	System	05 Sep 2020 07:31:26

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T02:31:22', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '728d3626-18ee-401a-9269-0df4531ba656'	System	05 Sep 2020 07:31:26
User entered '05 Sep 2020 02:31'	System	05 Sep 2020 07:31:26

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '04 Sep 2020 18:54'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 2'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:03', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered 'None (0)'	System	06 Sep 2020 02:20:27

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:09', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered 'None (0)'	System	06 Sep 2020 02:20:27

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641' User entered 'None (0)'	System	06 Sep 2020 02:20:27
	System	06 Sep 2020 02:20:27

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641' User entered 'None (0)'	System	06 Sep 2020 02:20:27
	System	06 Sep 2020 02:20:27

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:17', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered 'None (0)'	System	06 Sep 2020 02:20:27

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered 'None (0)'	System	06 Sep 2020 02:20:27

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:21', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered 'No (N)'	System	06 Sep 2020 02:20:27

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-05T21:20:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'b62f6102-681e-4f62-8337-817ff7f52641'	System	06 Sep 2020 02:20:27
User entered '05 Sep 2020 21:20'	System	06 Sep 2020 02:20:27

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 3'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'None (0)'	System	07 Sep 2020 02:54:25

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'None (0)'	System	07 Sep 2020 02:54:25

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:13', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'None (0)'	System	07 Sep 2020 02:54:25

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'None (0)'	System	07 Sep 2020 02:54:25

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:17', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'None (0)'	System	07 Sep 2020 02:54:25

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'None (0)'	System	07 Sep 2020 02:54:25

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:21', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered 'No (N)'	System	07 Sep 2020 02:54:25

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-06T21:54:23', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7e144e86-68fe-494c-a27a-0681b1d1f4f8'	System	07 Sep 2020 02:54:25
User entered '06 Sep 2020 21:54'	System	07 Sep 2020 02:54:25

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 4'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:50', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'None (0)'	System	08 Sep 2020 05:40:29

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:39:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'None (0)'	System	08 Sep 2020 05:40:29

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:40:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'No interference with activity (1)'	System	08 Sep 2020 05:40:29

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:40:08', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'No interference with activity (1)'	System	08 Sep 2020 05:40:29

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:40:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'None (0)'	System	08 Sep 2020 05:40:29

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:40:16', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'None (0)'	System	08 Sep 2020 05:40:29

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:40:23', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered 'No (N)'	System	08 Sep 2020 05:40:29

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T00:40:26', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'dda71fdd-16b6-48d0-af3f-00ca97ca977c'	System	08 Sep 2020 05:40:29
User entered '08 Sep 2020 00:40'	System	08 Sep 2020 05:40:29

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 5'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered 'None (0)'	System	09 Sep 2020 01:28:38

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered 'No interference with activity (1)'	System	09 Sep 2020 01:28:38

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:20', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e' User entered 'None (0)'	System	09 Sep 2020 01:28:38
	System	09 Sep 2020 01:28:38

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:23', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e' User entered 'None (0)'	System	09 Sep 2020 01:28:38
	System	09 Sep 2020 01:28:38

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:25', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e' User entered 'None (0)'	System	09 Sep 2020 01:28:38
	System	09 Sep 2020 01:28:38

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:28', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered 'None (0)'	System	09 Sep 2020 01:28:38

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered 'No (N)'	System	09 Sep 2020 01:28:38

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-08T20:28:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '108972ac-ecb9-401c-b7d4-d64094ee520e'	System	09 Sep 2020 01:28:38
User entered '08 Sep 2020 20:28'	System	09 Sep 2020 01:28:38

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 6'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:55', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'None (0)'	System	10 Sep 2020 05:01:14

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:57', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'None (0)'	System	10 Sep 2020 05:01:14

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:00:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'None (0)'	System	10 Sep 2020 05:01:14

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:01:01', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'None (0)'	System	10 Sep 2020 05:01:14

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:01:03', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'None (0)'	System	10 Sep 2020 05:01:14

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:01:05', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'None (0)'	System	10 Sep 2020 05:01:14

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:01:09', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered 'No (N)'	System	10 Sep 2020 05:01:14

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T00:01:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '681eafff-7915-4158-9824-400cb23e2eea'	System	10 Sep 2020 05:01:14
User entered '10 Sep 2020 00:01'	System	10 Sep 2020 05:01:14

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	04 Sep 2020 20:17:34
User entered 'Day 7'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:38', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'None (0)'	System	10 Sep 2020 23:36:03

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:40', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'None (0)'	System	10 Sep 2020 23:36:03

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:43', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'None (0)'	System	10 Sep 2020 23:36:03

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:46', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'None (0)'	System	10 Sep 2020 23:36:03

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:49', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'None (0)'	System	10 Sep 2020 23:36:03

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'None (0)'	System	10 Sep 2020 23:36:03

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:57', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered 'No (N)'	System	10 Sep 2020 23:36:03

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-09-10T18:35:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '4c9106f9-4d79-4c63-9f1f-2bf178fe6163'	System	10 Sep 2020 23:36:03
User entered '10 Sep 2020 18:35'	System	10 Sep 2020 23:36:03

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:17:34

US3272085

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:25:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:17:34

US3272085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:19:14

US3272085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '11 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:19:14

US3272085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 16:19:14

US3272085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:19:14

US3272085

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:19:16

US3272085

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:21
User entered 'I'	System	14 Sep 2020 16:19:16

US3272085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 23:06:56

US3272085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 23:06:56

US3272085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Sep 2020 23:06:56

US3272085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 23:06:56

US3272085

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 23:06:59

US3272085

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:42
User entered 'I'	System	18 Sep 2020 23:06:59

US3272085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:08:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 16:55:02

US3272085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:08:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '25 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 16:55:02

US3272085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:08:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Sep 2020 16:55:02

US3272085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:08:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 16:55:02

US3272085

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:08:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 16:54:51

US3272085

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:08:39
User entered 'I'	System	26 Sep 2020 16:54:51

US3272085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:44:20

US3272085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 20:44:20

US3272085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[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 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Oct 2020 20:44:20

US3272085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User entered 'VISIT3'	System	02 Oct 2020 20:44:20

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '14:03'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User entered '2 Oct 2020 14:03'	System	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '36.6' C	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '74'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User entered 'bpm'	System	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '16'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User entered 'breaths/min'	System	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '132'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User entered 'mmHg'	System	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '72'	(b) (4), (b) (6)	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User entered 'mmHg'	System	02 Oct 2020 20:45:39

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01

US3272085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01

US3272085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:45:53

US3272085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 20:45:53

US3272085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:46:35

US3272085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 20:46:35

US3272085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '14:14'	(b) (4), (b) (6)	02 Oct 2020 20:46:35

US3272085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User entered '2 Oct 2020 14:14'	System	02 Oct 2020 20:46:35

US3272085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:46:42

US3272085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:01
User entered 'I'	System	02 Oct 2020 20:46:42

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 64'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-07T00:01:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '03beed67-fedd-4d1e-829c-763c8b729163'	System	07 Oct 2020 05:02:58
User entered 'Yes (Y)'	System	07 Oct 2020 05:02:58

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-07T00:02:33', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '03beed67-feddd4d1e-829c-763c8b729163'	System	07 Oct 2020 05:02:58
User entered 'No (N)'	System	07 Oct 2020 05:02:58

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-07T00:02:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '03beed67-fedd-4d1e-829c-763c8b729163'	System	07 Oct 2020 05:02:58
User entered 'No (N)'	System	07 Oct 2020 05:02:58

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-07T00:02:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '03beed67-fedd-4d1e-829c-763c8b729163'	System	07 Oct 2020 05:02:58
User entered 'No (N)'	System	07 Oct 2020 05:02:58

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-07T00:02:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '03beed67-fedd-4d1e-829c-763c8b729163'	System	07 Oct 2020 05:02:58
User entered '07 Oct 2020 00:02:56'	System	07 Oct 2020 05:02:58

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 71'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-14T09:28:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6497f34a-657d-4e73-ab3c-ae4905704913'	System	14 Oct 2020 14:29:49
User entered 'Yes (Y)'	System	14 Oct 2020 14:29:49

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-14T09:29:05', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6497f34a-657d-4e73-ab3c-ae4905704913'	System	14 Oct 2020 14:29:49
User entered 'No (N)'	System	14 Oct 2020 14:29:49

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-14T09:29:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6497f34a-657d-4e73-ab3c-ae4905704913'	System	14 Oct 2020 14:29:49
User entered 'No (N)'	System	14 Oct 2020 14:29:49

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-14T09:29:23', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6497f34a-657d-4e73-ab3c-ae4905704913'	System	14 Oct 2020 14:29:49
User entered 'Yes (Y)'	System	14 Oct 2020 14:29:49

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-14T09:29:31', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6497f34a-657d-4e73-ab3c-ae4905704913'	System	14 Oct 2020 14:29:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Oct 2020 14:29:49

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-14T09:29:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6497f34a-657d-4e73-ab3c-ae4905704913'	System	14 Oct 2020 14:29:49
User entered '14 Oct 2020 09:29:39'	System	14 Oct 2020 14:29:49

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 78'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-21T02:37:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f1526a96-0639-427e-b5f1-4011175240e0'	System	21 Oct 2020 07:38:35
User entered 'Yes (Y)'	System	21 Oct 2020 07:38:35

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-21T02:37:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f1526a96-0639-427e-b5f1-4011175240e0'	System	21 Oct 2020 07:38:35
User entered 'No (N)'	System	21 Oct 2020 07:38:35

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-21T02:38:00', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f1526a96-0639-427e-b5f1-4011175240e0'	System	21 Oct 2020 07:38:35
User entered 'No (N)'	System	21 Oct 2020 07:38:35

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-21T02:38:17', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f1526a96-0639-427e-b5f1-4011175240e0'	System	21 Oct 2020 07:38:35
User entered 'No (N)'	System	21 Oct 2020 07:38:35

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-10-21T02:38:31', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f1526a96-0639-427e-b5f1-4011175240e0' User entered '21 Oct 2020 02:38:31'	System	21 Oct 2020 07:38:35
	System	21 Oct 2020 07:38:35

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 92'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-11-04T00:07:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '114129da-bdea-4c65-92eb-f94302f8041e'	System	04 Nov 2020 06:07:39
User entered 'No (N)'	System	04 Nov 2020 06:07:39

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-11-04T00:07:29', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '114129da-bdea-4c65-92eb-f94302f8041e'	System	04 Nov 2020 06:07:39
User entered 'No (N)'	System	04 Nov 2020 06:07:39

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-11-04T00:07:35', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '114129da-bdea-4c65-92eb-f94302f8041e'	System	04 Nov 2020 06:07:39
User entered '04 Nov 2020 00:07:35'	System	04 Nov 2020 06:07:39

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 99'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-11-11T10:02:41', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'c95e32b9-6bc2-4e4f-96a0-7913e6a4e696'	System	11 Nov 2020 16:03:18
User entered 'No (N)'	System	11 Nov 2020 16:03:18

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-11-11T10:02:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'c95e32b9-6bc2-4e4f-96a0-7913e6a4e696'	System	11 Nov 2020 16:03:18
User entered 'Yes (Y)'	System	11 Nov 2020 16:03:18

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-11-11T10:02:58', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'c95e32b9-6bc2-4e4f-96a0-7913e6a4e696'	System	11 Nov 2020 16:03:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 16:03:18

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-11-11T10:03:02', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'c95e32b9-6bc2-4e4f-96a0-7913e6a4e696'	System	11 Nov 2020 16:03:18
User entered '11 Nov 2020 10:03:02'	System	11 Nov 2020 16:03:18

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:41:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered 'Day 106'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Please 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 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Please 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 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Please 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 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 22:16:40

US3272085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:21:32
Data entry locked.	System	07 Aug 2020 22:16:40
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 22:16:40

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2020-11-25T14:05:49', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ab24a370-eac6-4909-a9b9-e0dd44f6047b'	System	25 Nov 2020 20:06:51
User entered 'Yes (Y)'	System	25 Nov 2020 20:06:51

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2020-11-25T14:05:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ab24a370-eac6-4909-a9b9-e0dd44f6047b'	System	25 Nov 2020 20:06:51
User entered 'No (N)'	System	25 Nov 2020 20:06:51

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2020-11-25T14:06:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ab24a370-eac6-4909-a9b9-e0dd44f6047b'	System	25 Nov 2020 20:06:51
User entered 'No (N)'	System	25 Nov 2020 20:06:51

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2020-11-25T14:06:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ab24a370-eac6-4909-a9b9-e0dd44f6047b'	System	25 Nov 2020 20:06:51
User entered 'No (N)'	System	25 Nov 2020 20:06:51

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-11-25T14:06:49', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ab24a370-eac6-4909-a9b9-e0dd44f6047b'	System	25 Nov 2020 20:06:51
User entered '25 Nov 2020 14:06:49'	System	25 Nov 2020 20:06:51

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2020-11-29T02:57:57', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'c3c2589f-3de6-4fb2-aa6a-a71fa8d27ef4'	System	29 Nov 2020 08:58:08
User entered 'No (N)'	System	29 Nov 2020 08:58:08

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2020-11-29T02:58:03', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'c3c2589f-3de6-4fb2-aa6a-a71fa8d27ef4'	System	29 Nov 2020 08:58:08
User entered 'No (N)'	System	29 Nov 2020 08:58:08

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-11-29T02:58:06', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'c3c2589f-3de6-4fb2-aa6a-a71fa8d27ef4'	System	29 Nov 2020 08:58:08
User entered '29 Nov 2020 02:58:06'	System	29 Nov 2020 08:58:08

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2020-12-06T02:28:48', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '10e47d0c-c178-4ac2-861a-db23e70fa9fb'	System	06 Dec 2020 08:29:03
User entered 'No (N)'	System	06 Dec 2020 08:29:03

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2020-12-06T02:28:55', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '10e47d0c-c178-4ac2-861a-db23e70fa9fb'	System	06 Dec 2020 08:29:03
User entered 'No (N)'	System	06 Dec 2020 08:29:03

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-12-06T02:28:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '10e47d0c-c178-4ac2-861a-db23e70fa9fb'	System	06 Dec 2020 08:29:03
User entered '06 Dec 2020 02:28:59'	System	06 Dec 2020 08:29:03

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2020-12-17T12:55:54', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7f83248d-b0ae-4363-989b-a67644f627b4'	System	17 Dec 2020 18:56:07
User entered 'No (N)'	System	17 Dec 2020 18:56:07

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2020-12-17T12:56:01', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7f83248d-b0ae-4363-989b-a67644f627b4'	System	17 Dec 2020 18:56:07
User entered 'No (N)'	System	17 Dec 2020 18:56:07

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-12-17T12:56:04', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7f83248d-b0ae-4363-989b-a67644f627b4'	System	17 Dec 2020 18:56:07
User entered '17 Dec 2020 12:56:04'	System	17 Dec 2020 18:56:07

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2020-12-20T03:06:07', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3a65daee-53be-4fb8-9b88-037dcd4af67e'	System	20 Dec 2020 09:06:46
User entered 'No (N)'	System	20 Dec 2020 09:06:46

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2020-12-20T03:06:36', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3a65daee-53be-4fb8-9b88-037dcd4af67e'	System	20 Dec 2020 09:06:46
User entered 'No (N)'	System	20 Dec 2020 09:06:46

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-12-20T03:06:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3a65daee-53be-4fb8-9b88-037dcd4af67e'	System	20 Dec 2020 09:06:46
User entered '20 Dec 2020 03:06:42'	System	20 Dec 2020 09:06:46

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2020-12-27T02:07:34', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '01d91407-8354-4bc6-875c-5693addfcb56'	System	27 Dec 2020 08:07:49
User entered 'No (N)'	System	27 Dec 2020 08:07:49

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2020-12-27T02:07:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '01d91407-8354-4bc6-875c-5693addfcb56'	System	27 Dec 2020 08:07:49
User entered 'No (N)'	System	27 Dec 2020 08:07:49

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2020-12-27T02:07:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '01d91407-8354-4bc6-875c-5693addfcb56'	System	27 Dec 2020 08:07:49
User entered '27 Dec 2020 02:07:45'	System	27 Dec 2020 08:07:49

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-01-10T18:37:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '38a659de-32c6-4757-a1e9-02ba69ec9d0c'	System	11 Jan 2021 00:38:22
User entered 'Yes (Y)'	System	11 Jan 2021 00:38:22

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-01-10T18:37:48', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '38a659de-32c6-4757-a1e9-02ba69ec9d0c'	System	11 Jan 2021 00:38:22
User entered 'No (N)'	System	11 Jan 2021 00:38:22

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-01-10T18:37:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '38a659de-32c6-4757-a1e9-02ba69ec9d0c'	System	11 Jan 2021 00:38:22
User entered 'No (N)'	System	11 Jan 2021 00:38:22

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-01-10T18:37:59', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '38a659de-32c6-4757-a1e9-02ba69ec9d0c'	System	11 Jan 2021 00:38:22
User entered 'Yes (Y)'	System	11 Jan 2021 00:38:22

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Please 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 (a5a7983321c3e006)', Time: '2021-01-10T18:38:07', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '38a659de-32c6-4757-a1e9-02ba69ec9d0c'	System	11 Jan 2021 00:38:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Jan 2021 00:38:22

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-01-10T18:38:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '38a659de-32c6-4757-a1e9-02ba69ec9d0c'	System	11 Jan 2021 00:38:22
User entered '10 Jan 2021 18:38:10'	System	11 Jan 2021 00:38:22

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-01-17T02:30:54', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'eceed60c-4e3e-4c55-ac44-42fce7fe58f8'	System	17 Jan 2021 08:31:36
User entered 'Yes (Y)'	System	17 Jan 2021 08:31:36

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-01-17T02:31:00', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'eceed60c-4e3e-4c55-ac44-42fce7fe58f8'	System	17 Jan 2021 08:31:36
User entered 'No (N)'	System	17 Jan 2021 08:31:36

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-01-17T02:31:06', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'eceed60c-4e3e-4c55-ac44-42fce7fe58f8'	System	17 Jan 2021 08:31:36
User entered 'No (N)'	System	17 Jan 2021 08:31:36

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-01-17T02:31:14', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'eceed60c-4e3e-4c55-ac44-42fce7fe58f8'	System	17 Jan 2021 08:31:36
User entered 'Yes (Y)'	System	17 Jan 2021 08:31:36

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Please 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 (a5a7983321c3e006)', Time: '2021-01-17T02:31:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'eceed60c-4e3e-4c55-ac44-42fce7fe58f8'	System	17 Jan 2021 08:31:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Jan 2021 08:31:36

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-01-17T02:31:27', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'eceed60c-4e3e-4c55-ac44-42fce7fe58f8'	System	17 Jan 2021 08:31:36
User entered '17 Jan 2021 02:31:27'	System	17 Jan 2021 08:31:36

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-01-24T10:51:07', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6bc32dfd-282f-423d-b883-a467ba6b7e83'	System	24 Jan 2021 16:51:44
User entered 'Yes (Y)'	System	24 Jan 2021 16:51:44

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-01-24T10:51:10', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6bc32dfd-282f-423d-b883-a467ba6b7e83'	System	24 Jan 2021 16:51:44
User entered 'No (N)'	System	24 Jan 2021 16:51:44

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-01-24T10:51:13', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6bc32dfd-282f-423d-b883-a467ba6b7e83'	System	24 Jan 2021 16:51:44
User entered 'No (N)'	System	24 Jan 2021 16:51:44

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-01-24T10:51:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6bc32dfd-282f-423d-b883-a467ba6b7e83'	System	24 Jan 2021 16:51:44
User entered 'No (N)'	System	24 Jan 2021 16:51:44

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-01-24T10:51:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '6bc32dfd-282f-423d-b883-a467ba6b7e83'	System	24 Jan 2021 16:51:44
User entered '24 Jan 2021 10:51:42'	System	24 Jan 2021 16:51:44

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-01-31T02:23:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '11030cba-1209-4721-a10f-876ecbae4a89'	System	31 Jan 2021 08:23:59
User entered 'No (N)'	System	31 Jan 2021 08:23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-01-31T02:23:51', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '11030cba-1209-4721-a10f-876ecbae4a89'	System	31 Jan 2021 08:23:59
User entered 'No (N)'	System	31 Jan 2021 08:23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-01-31T02:23:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '11030cba-1209-4721-a10f-876ecbae4a89'	System	31 Jan 2021 08:23:59
User entered '31 Jan 2021 02:23:56'	System	31 Jan 2021 08:23:59

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-02-07T01:51:49', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3a40253d-af52-4487-b8ed-673cacc921de'	System	07 Feb 2021 07:52:01
User entered 'No (N)'	System	07 Feb 2021 07:52:01

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-02-07T01:51:53', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3a40253d-af52-4487-b8ed-673cacc921de'	System	07 Feb 2021 07:52:01
User entered 'No (N)'	System	07 Feb 2021 07:52:01

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-02-07T01:51:56', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '3a40253d-af52-4487-b8ed-673cacc921de'	System	07 Feb 2021 07:52:01
User entered '07 Feb 2021 01:51:56'	System	07 Feb 2021 07:52:01

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-02-15T10:44:12', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ae964187-5397-4f7e-9b3c-08f2bcbda028'	System	15 Feb 2021 16:44:31
User entered 'No (N)'	System	15 Feb 2021 16:44:31

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-02-15T10:44:17', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ae964187-5397-4f7e-9b3c-08f2bcbda028'	System	15 Feb 2021 16:44:31
User entered 'No (N)'	System	15 Feb 2021 16:44:31

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-02-15T10:44:28', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'ae964187-5397-4f7e-9b3c-08f2bcbda028'	System	15 Feb 2021 16:44:31
User entered '15 Feb 2021 10:44:28'	System	15 Feb 2021 16:44:31

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-02-21T03:59:09', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '244a42b6-ef85-4cb5-bf23-f67fce64790a'	System	21 Feb 2021 09:59:22
User entered 'No (N)'	System	21 Feb 2021 09:59:22

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-02-21T03:59:15', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '244a42b6-ef85-4cb5-bf23-f67fce64790a'	System	21 Feb 2021 09:59:22
User entered 'No (N)'	System	21 Feb 2021 09:59:22

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-02-21T03:59:18', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '244a42b6-ef85-4cb5-bf23-f67fce64790a'	System	21 Feb 2021 09:59:22
User entered '21 Feb 2021 03:59:18'	System	21 Feb 2021 09:59:22

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-02-28T02:30:19', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '30e548b1-ca38-408e-8ddb-1086c0367174'	System	28 Feb 2021 08:30:30
User entered 'No (N)'	System	28 Feb 2021 08:30:30

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-02-28T02:30:24', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '30e548b1-ca38-408e-8ddb-1086c0367174'	System	28 Feb 2021 08:30:30
User entered 'No (N)'	System	28 Feb 2021 08:30:30

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-02-28T02:30:27', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '30e548b1-ca38-408e-8ddb-1086c0367174'	System	28 Feb 2021 08:30:30
User entered '28 Feb 2021 02:30:27'	System	28 Feb 2021 08:30:30

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-03-07T00:02:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f676fde1-9f68-421f-bebe-5e071d51fb83'	System	07 Mar 2021 06:03:03
User entered 'No (N)'	System	07 Mar 2021 06:03:03

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-03-07T00:02:45', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f676fde1-9f68-421f-bebe-5e071d51fb83'	System	07 Mar 2021 06:03:03
User entered 'No (N)'	System	07 Mar 2021 06:03:03

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-03-07T00:02:55', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f676fde1-9f68-421f-bebe-5e071d51fb83'	System	07 Mar 2021 06:03:03
User entered '07 Mar 2021 00:02:55'	System	07 Mar 2021 06:03:03

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-03-16T12:50:28', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7de5b91b-cef2-4048-b747-8f5ed48ceb1f'	System	16 Mar 2021 17:50:40
User entered 'No (N)'	System	16 Mar 2021 17:50:40

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-03-16T12:50:25', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7de5b91b-cef2-4048-b747-8f5ed48ceb1f'	System	16 Mar 2021 17:50:40
User entered 'No (N)'	System	16 Mar 2021 17:50:40

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-03-16T12:50:34', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '7de5b91b-cef2-4048-b747-8f5ed48ceb1f' User entered '16 Mar 2021 12:50:34'	System	16 Mar 2021 17:50:40
	System	16 Mar 2021 17:50:40

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-03-24T19:59:36', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '9fcbdde3-971d-4cd8-9100-b2513d86bd13'	System	25 Mar 2021 00:59:50
User entered 'No (N)'	System	25 Mar 2021 00:59:50

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-03-24T19:59:43', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '9fcbbde3-971d-4cd8-9100-b2513d86bd13'	System	25 Mar 2021 00:59:50
User entered 'No (N)'	System	25 Mar 2021 00:59:50

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-03-24T19:59:47', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '9fcbbde3-971d-4cd8-9100-b2513d86bd13'	System	25 Mar 2021 00:59:50
User entered '24 Mar 2021 19:59:47'	System	25 Mar 2021 00:59:50

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-03-28T03:50:14', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '63872d71-8d50-4f3a-94c4-b37efc6097ba'	System	28 Mar 2021 08:50:27
User entered 'No (N)'	System	28 Mar 2021 08:50:27

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-03-28T03:50:20', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '63872d71-8d50-4f3a-94c4-b37efc6097ba'	System	28 Mar 2021 08:50:27
User entered 'No (N)'	System	28 Mar 2021 08:50:27

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-03-28T03:50:25', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '63872d71-8d50-4f3a-94c4-b37efc6097ba'	System	28 Mar 2021 08:50:27
User entered '28 Mar 2021 03:50:25'	System	28 Mar 2021 08:50:27

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-04-04T11:12:30', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f37c61ff-61f2-4f9a-b275-43bc379d0213'	System	04 Apr 2021 16:12:44
User entered 'No (N)'	System	04 Apr 2021 16:12:44

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-04-04T11:12:39', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f37c61ff-61f2-4f9a-b275-43bc379d0213'	System	04 Apr 2021 16:12:44
User entered 'No (N)'	System	04 Apr 2021 16:12:44

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-04-04T11:12:42', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: 'f37c61ff-61f2-4f9a-b275-43bc379d0213'	System	04 Apr 2021 16:12:44
User entered '04 Apr 2021 11:12:42'	System	04 Apr 2021 16:12:44

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-04-26T21:27:07', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '12c1b686-fb2f-42d2-8dca-10ec782829ff'	System	27 Apr 2021 02:27:47
User entered 'No (N)'	System	27 Apr 2021 02:27:47

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-04-26T21:27:29', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '12c1b686-fb2f-42d2-8dca-10ec782829ff'	System	27 Apr 2021 02:27:47
User entered 'Yes (Y)'	System	27 Apr 2021 02:27:47

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Please 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 (a5a7983321c3e006)', Time: '2021-04-26T21:27:31', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '12c1b686-fb2f-42d2-8dca-10ec782829ff'	System	27 Apr 2021 02:27:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Apr 2021 02:27:47

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-04-26T21:27:35', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '12c1b686-fb2f-42d2-8dca-10ec782829ff'	System	27 Apr 2021 02:27:47
User entered '26 Apr 2021 21:27:35'	System	27 Apr 2021 02:27:47

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[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 (a5a7983321c3e006)', Time: '2021-05-02T02:57:31', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '87e33634-c6c8-434e-9222-74bef7b1928c'	System	02 May 2021 07:57:42
User entered 'No (N)'	System	02 May 2021 07:57:42

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Have you been exposed to someone with 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 (a5a7983321c3e006)', Time: '2021-05-02T02:57:35', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '87e33634-c6c8-434e-9222-74bef7b1928c'	System	02 May 2021 07:57:42
User entered 'No (N)'	System	02 May 2021 07:57:42

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-05-02T02:57:40', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '87e33634-c6c8-434e-9222-74bef7b1928c'	System	02 May 2021 07:57:42
User entered '02 May 2021 02:57:40'	System	02 May 2021 07:57:42

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:21:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 16:21:32

US3272085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:25:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:21:32
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 16:21:32

US3272085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:25:43

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 09:01:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-02-28T02:30:07', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '8ef49a7f-fb71-4630-9ea2-58258c947afb'	System	28 Feb 2021 08:30:18
User entered 'No (N)'	System	28 Feb 2021 08:30:18

US3272085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:25:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:01:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a5a7983321c3e006)', Time: '2021-02-28T02:30:11', User OID: 'PatientReportedOutcome (US3272085)', ODM File OID: '8ef49a7f-fb71-4630-9ea2-58258c947afb' User entered '28 Feb 2021 02:30:11'	System	28 Feb 2021 08:30:18
	System	28 Feb 2021 08:30:18

US3272085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 13:28:44

US3272085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '27 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 13:28:44

US3272085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Oct 2020 13:28:44

US3272085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 13:28:44

US3272085

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 13:28:50

US3272085

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:49:09
User entered 'I'	System	28 Oct 2020 13:28:50

US3272085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:18:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 18:20:02

US3272085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:18:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '1 Dec 2020'	(b) (4), (b) (6)	09 Mar 2021 18:20:02

US3272085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:18:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Mar 2021 18:20:02

US3272085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:18:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 18:20:02

US3272085

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:18:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 21:00:22

US3272085

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:18:41
User entered 'I'	System	02 Feb 2021 21:00:22

US3272085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:19:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 18:20:26

US3272085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:19:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '30 Dec 2020'	(b) (4), (b) (6)	09 Mar 2021 18:20:26

US3272085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:19:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Mar 2021 18:20:26

US3272085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:19:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 18:20:26

US3272085

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:19:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 21:00:30

US3272085

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:19:01
User entered 'I'	System	02 Feb 2021 21:00:30

US3272085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 21:00:47

US3272085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '01 Feb 2021'	(b) (4), (b) (6)	02 Feb 2021 21:00:47

US3272085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Feb 2021 21:00:47

US3272085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 21:00:47

US3272085

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 21:00:50

US3272085

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:34:53
User entered 'I'	System	02 Feb 2021 21:00:50

US3272085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:28:41

US3272085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '15 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:28:41

US3272085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[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 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Mar 2021 20:28:41

US3272085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User entered 'VISIT4'	System	19 Mar 2021 20:28:41

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'No (N)'	Ashley Bell (b) (4)	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User entered empty.	System	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User entered empty.	System	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User entered empty.	System	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User entered empty.	System	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User entered empty.	System	30 Mar 2021 23:50:21

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02

US3272085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02

US3272085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:29:00

US3272085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '15 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:29:00

US3272085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:29:48

US3272085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '15 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:29:48

US3272085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered '14:28'	(b) (4), (b) (6)	19 Mar 2021 20:29:48

US3272085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User entered '15 Mar 2021 14:28'	System	19 Mar 2021 20:29:48

US3272085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:29:51

US3272085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:02
User entered 'I'	System	19 Mar 2021 20:29:51

US3272085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 14:05:33

US3272085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '30 Mar 2021'	(b) (4), (b) (6)	06 Apr 2021 14:05:33

US3272085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Apr 2021 14:05:33

US3272085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 14:05:33

US3272085

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 14:05:38

US3272085

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 14:05:38

US3272085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 19:40:59

US3272085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '29 Apr 2021'	(b) (4), (b) (6)	03 May 2021 19:40:59

US3272085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 May 2021 19:40:59

US3272085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 19:40:59

US3272085

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 19:41:04

US3272085

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 19:41:04

US3272085

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

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 22:45:02

US3272085

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

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 22:45:02

US3272085

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

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[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 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Jan 2021 22:45:02

US3272085

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

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 22:45:02

US3272085

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

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 22:45:34

US3272085

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

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[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 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 13:35:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:57:14

US3272085

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

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 22:45:34

US3272085

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

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 15:57:59
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 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 13:35:47
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	22 Apr 2021 13:35:28
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).		22 Apr 2021 06:39:20
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:57:14

US3272085

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

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 22:45:34

US3272085

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

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 22:45:34

US3272085

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

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:44:47
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 22:45:34

US3272085

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

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:44:47
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 22:45:34

US3272085

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

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 22:46:32
User entered 'No (N)'		19 Jan 2021 22:45:34

US3272085

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

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered '1'	System	19 Jan 2021 22:45:34

US3272085

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

Form: Unblinding

Generated On: 09 Jun 2021 16:25:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'I'	System	19 Jan 2021 22:46:32
User entered empty.	System	19 Jan 2021 22:45:34

US3272085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered empty.	System	19 Jan 2021 22:48:57
DataPoint set to visible.	System	19 Jan 2021 22:46:32

US3272085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered empty.	System	19 Jan 2021 22:48:57
DataPoint set to visible.	System	19 Jan 2021 22:46:32

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User accepted default value 'Pre-Dose (PREDOSE)'		19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '14:36'	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered '19 Jan 2021 14:36'	System	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '36.7' C	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '74'	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'bpm'	System	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '14'	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'breaths/min'	System	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '124'	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'mmHg'	System	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '81'	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'mmHg'	System	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	19 Jan 2021 22:48:57

US3272085

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:25:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered empty.	System	19 Jan 2021 22:48:57
DataPoint set to visible.	System	19 Jan 2021 22:46:32

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User accepted default value 'Post-Dose (POSTDOSE)'		19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '16:25'	(b) (4), (b) (6)	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered '19 Jan 2021 16:25'	System	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '36.7' C	(b) (4), (b) (6)	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '78'	(b) (4), (b) (6)	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'bpm'	System	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '18'	(b) (4), (b) (6)	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'breaths/min'	System	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '131'	(b) (4), (b) (6)	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'mmHg'	System	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '75'	(b) (4), (b) (6)	19 Jan 2021 22:49:47

US3272085

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'mmHg'	System	19 Jan 2021 22:49:47

US3272085

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 22:49:56

US3272085

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 22:49:56

US3272085

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

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 22:50:33

US3272085

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

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 22:50:33

US3272085

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

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 22:50:33

US3272085

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

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'mRNA-1273'	System	19 Jan 2021 22:50:33
DataPoint set to visible.	System	19 Jan 2021 22:46:32

US3272085

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

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 22:50:33

US3272085

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

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '15:49'	(b) (4), (b) (6)	19 Jan 2021 22:50:33

US3272085

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

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered '19 Jan 2021 15:49'	System	19 Jan 2021 22:50:33

US3272085

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

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	19 Jan 2021 22:50:33

US3272085

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

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'ONCE'	System	19 Jan 2021 22:50:33

US3272085

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

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 22:50:33

US3272085

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 22:46:04

US3272085

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 22:46:04

US3272085

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '14:19'	(b) (4), (b) (6)	19 Jan 2021 22:46:04

US3272085

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered '19 Jan 2021 14:19'	System	19 Jan 2021 22:46:04

US3272085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 22:46:18

US3272085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:25:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 22:46:18

US3272085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:25:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '14:21'	(b) (4), (b) (6)	19 Jan 2021 22:46:18

US3272085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered '19 Jan 2021 14:21'	System	19 Jan 2021 22:46:18

US3272085

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

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 22:50:37

US3272085

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

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:49
User entered '1'	System	19 Jan 2021 22:50:37

US3272085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:30:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:21:05

US3272085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:30:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:21:05

US3272085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:30:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Jan 2021 18:21:05

US3272085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:30:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:21:05

US3272085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:30:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:21:11

US3272085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:30:56
User entered 'I'	System	27 Jan 2021 18:21:11

US3272085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:30:56
User entered 'I'	System	27 Jan 2021 18:21:11
DataPoint set to visible.	System	27 Jan 2021 18:21:11

US3272085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 20:50:32

US3272085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 20:50:32

US3272085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Feb 2021 20:50:32

US3272085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'OLD29'	System	17 Feb 2021 20:50:32

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User accepted default value 'Pre-Dose (PREDOSE)'		17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '16:11'	(b) (4), (b) (6)	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered '16 Feb 2021 16:11'	System	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '36.5' C	(b) (4), (b) (6)	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '81'	(b) (4), (b) (6)	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'bpm'	System	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '15'	(b) (4), (b) (6)	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'breaths/min'	System	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '124'	(b) (4), (b) (6)	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'mmHg'	System	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '89'	(b) (4), (b) (6)	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'mmHg'	System	17 Feb 2021 20:51:05

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User accepted default value 'Post-Dose (POSTDOSE)'		17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '17:14'	(b) (4), (b) (6)	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered '16 Feb 2021 17:14'	System	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '36.9' C	(b) (4), (b) (6)	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '76'	(b) (4), (b) (6)	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'bpm'	System	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '16'	(b) (4), (b) (6)	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'breaths/min'	System	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '125'	(b) (4), (b) (6)	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'mmHg'	System	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '82'	(b) (4), (b) (6)	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'mmHg'	System	17 Feb 2021 20:52:11

US3272085

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 20:51:19

US3272085

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 20:51:19

US3272085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 20:51:35

US3272085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 20:51:35

US3272085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 20:51:35

US3272085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'mRNA-1273'	System	17 Feb 2021 20:51:35
DataPoint set to visible.	System	27 Jan 2021 18:21:11

US3272085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 20:51:35

US3272085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '16:37'	(b) (4), (b) (6)	17 Feb 2021 20:51:35

US3272085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered '16 Feb 2021 16:37'	System	17 Feb 2021 20:51:35

US3272085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	17 Feb 2021 20:51:35

US3272085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'ONCE'	System	17 Feb 2021 20:51:35

US3272085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:25:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 20:51:35

US3272085

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 20:51:39

US3272085

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:39:55
User entered 'I'	System	17 Feb 2021 20:51:39

US3272085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:33:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 01:02:03

US3272085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:33:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '23 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 01:02:03

US3272085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:33:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Feb 2021 01:02:03

US3272085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:25:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:33:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 01:02:03

US3272085

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:33:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 01:02:07

US3272085

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:25:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:33:53
User entered 'I'	System	25 Feb 2021 01:02:07

US3272085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:27:27

US3272085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '15 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:27:27

US3272085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[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 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Mar 2021 20:27:27

US3272085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:25:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User entered 'OLD57'	System	19 Mar 2021 20:27:27

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '15 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '14:06'	(b) (4), (b) (6)	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User entered '15 Mar 2021 14:06'	System	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '36.5' C	(b) (4), (b) (6)	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '72'	(b) (4), (b) (6)	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User entered 'bpm'	System	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '13'	(b) (4), (b) (6)	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User entered 'breaths/min'	System	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '124'	(b) (4), (b) (6)	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User entered 'mmHg'	System	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '72'	(b) (4), (b) (6)	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User entered 'mmHg'	System	19 Mar 2021 20:28:00

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17

US3272085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:25:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17

US3272085

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:28:08

US3272085

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:25:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '15 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:28:08

US3272085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 20:28:23

US3272085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '15 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 20:28:23

US3272085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '14:28'	(b) (4), (b) (6)	19 Mar 2021 20:28:23

US3272085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:25:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:44:17
User entered '15 Mar 2021 14:28'	System	19 Mar 2021 20:28:23

US3272085

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:00:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:15:06
User signature succeeded.	Adam Brosz (b) (4)	27 Nov 2020 16:27:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:24:20
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:19

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:34
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:13
User entered	System	16 Oct 2020 00:29:10
'USA-US070-2020-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	16 Oct 2020 00:29:10

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:36
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 19:06:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Chest wall pain - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 16:35:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 16:35:20
Data point term sent to Coder	System	02 Nov 2020 21:30:37
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	02 Nov 2020 21:30:08
Coding entries removed.	Kayla Flege (b) (4)	02 Nov 2020 21:29:50
Signature has been broken.	Kayla Flege (b) (4)	02 Nov 2020 21:29:50
User entered 'WORSENING INTERMITTENT CHEST WALL PAIN Non Cardiac' reason for change: Data Entry Error	Kayla Flege (b) (4)	02 Nov 2020 21:29:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 06:28:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Chest wall pain - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 00:16:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	16 Oct 2020 00:16:40
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
Data point term sent to Coder	System	15 Oct 2020 16:40:39
User entered 'Worsening Intermittent chest wall pain'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:39
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Yes (Y)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:41
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'No (N)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:43
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'No (N)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:45
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
Signature has been broken.	Kayla Flege (b) (4)	19 Nov 2020 19:48:11
User entered '07 Oct 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 19:48:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '7 Oct 2020'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:48
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered empty.	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:40:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:50
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 21:09:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:09:09
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Dec 2020 22:51:51
Signature has been broken.	Kayla Flege (b) (4)	01 Dec 2020 22:51:37
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Dec 2020 22:51:37
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Yes (Y)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:53
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 21:09:09
User entered '31 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:09:09
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:35:37
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	Whitney West (b) (4)	20 Jan 2021 00:42:20
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:55:22
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 18:03:13
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	01 Dec 2020 22:51:51
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	01 Dec 2020 22:51:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' answered with 'getting better, but not completely resolved at this time.' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	01 Dec 2020 22:50:32
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:14:52
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:46:52
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. Please leave query open until information is available.' answered with 'left message for pt' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	19 Nov 2020 19:52:43
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:50:02
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 Nov 2020 13:50:02
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 'not yet available' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 22:50:04
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)	06 Nov 2020 13:09:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	29 Oct 2020 16:48:10
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ongoing no end date' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 20:14:59
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)	23 Oct 2020 19:13:55
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered empty.	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:55
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered empty.	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:54:49
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 19:13:24
User entered empty.	System	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:56
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:29:58
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Yes (Y)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:01
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:03
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:06
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'I'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:08
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '9 Oct 2020'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:11
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '10 Oct 2020'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:13
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'No (N)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:15
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered empty.	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:17
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:19
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:20
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

US3272085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:25:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:23
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:25
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:28
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 04 Sep 2020, please update the action taken with mRNA-1273 or placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:48:16
Query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 04 Sep 2020, please update the action taken with mRNA-1273 or placebo from none to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 20:15:23
Signature has been broken.	(b) (4), (b) (6)	28 Oct 2020 20:15:15
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 20:15:15
User opened query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 04 Sep 2020, please update the action taken with mRNA-1273 or placebo from none to not applicable.' (Site from Safety).		23 Oct 2020 19:13:39
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'None (NONE)'	Andrea Clement (b) (4) (b) (4)	15 Oct 2020 16:40:21

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:30
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:32
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'I'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 14:31:07
User closed query 'please verify procedures per concomitant procedures tab' (Site from CRA).	(b) (4)	30 Apr 2021 14:30:53
Query 'please verify procedures per concomitant procedures tab' answered with 'Data entry error. Subject had no therapeutic procedures. ' (Site from CRA).	Whitney West (b) (4)	30 Apr 2021 14:24:30
User entered '0' reason for change: Data Entry Error	Whitney West (b) (4)	30 Apr 2021 14:23:29
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 20:20:34
DataPoint Verified.	(b) (4)	29 Apr 2021 20:18:11
DataPoint Un-verified.	(b) (4)	29 Apr 2021 20:10:09
DataPoint Verified.	(b) (4)	29 Apr 2021 20:09:20
Signature has been broken.	(b) (4)	29 Apr 2021 18:52:27
User entered '1' reason for change: Data Entry Error	(b) (4)	29 Apr 2021 18:52:27
User opened query 'please verify procedures per concomitant procedures tab' (Site from CRA).	(b) (4)	26 Apr 2021 16:32:50
DataPoint Un-verified.	(b) (4)	26 Apr 2021 16:30:49
DataPoint Verified.	(b) (4)	26 Apr 2021 16:30:42
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered '0'	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:44
Signature has been broken.		15 Apr 2021 21:09:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		15 Apr 2021 21:09:09
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 15:06:42
Query 'PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline.' answered with 'not going to resolve' (Site from Safety).		03 Jan 2021 23:33:28
Signature has been broken.		03 Jan 2021 23:33:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error		03 Jan 2021 23:33:03
User opened query 'PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline.' (Site from Safety).		06 Dec 2020 19:13:38
User closed query 'PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline.PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 18:03:16

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[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline.PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline.' answered with 'getting better but still has not resolved.' (Site from Safety).	Kayla Flege (b) (4)	01 Dec 2020 22:51:22
User opened query 'PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline.PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:15:05
User closed query 'PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:46:56
Query 'PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline.' answered with 'left message for pt' (Site from Safety).	Kayla Flege (b) (4)	19 Nov 2020 19:52:30
User opened query 'PV Query: Please provide the final event outcome, when available. Please leave query open until resolution is obtained or the subject reaches a new baseline.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 13:50:51
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 Nov 2020 13:50:51
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 'still ongoing ' (Site from Safety).	Ashley Bell (b) (4)	15 Nov 2020 20:35:10

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:09:56
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).		29 Oct 2020 16:48:24
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 'not resolved yet' (Site from Safety).		28 Oct 2020 20:15:38
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).		23 Oct 2020 19:14:12
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Andrea Clement (b) (4) (b) (4)	15 Oct 2020 16:40:21

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:52
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered empty.	Andrea Clement (b) (4)	15 Oct 2020 16:40:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:30:54
User closed query 'Per DM CLR: SAE Narrative = HE STATES CARDIAC ENZYMES WERE NORMAL. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.'	(b) (4), (b) (6)	18 Feb 2021 12:45:39
(Site from DM).		
Query 'Per DM CLR: SAE Narrative = HE STATES CARDIAC ENZYMES WERE NORMAL. However this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.'		16 Feb 2021 23:58:07
' answered with 'data correct' (Site from DM).		
User opened query 'Per DM CLR: SAE Narrative = HE STATES CARDIAC ENZYMES WERE NORMAL. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.'	(b) (4), (b) (6)	24 Jan 2021 12:45:14
(Site from DM).		
User closed query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information on BLOOD Work up is available. Update eCRF as appropriate'		
(Site from DM).		
	(b) (4), (b) (6)	28 Dec 2020 16:10:09

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information on BLOOD Work up is available. Update eCRF as appropriate ' answered with '09OCT2020: Glucose 210, BUN 24, Creatinine 1.24, Sodium 140, Potassium 3.6, Chloride: 105, CO2 26.0, Anion Gap 13, Calcium 8.4, Albumin 3.8, AST 23, ALT 33, GFR 64, Total protein 6.8, Globulin 3.0, Alkaline Phos: 60, Total Bilirubin 1.1, WBC 5.9, RBC 6.35, Hgb 13.7, Hct 40.0, MCV 63, MCH 21.6, MCHC 34.3, RDW 16, Platelet Count 226, MPV 9.9, Neutrophils percent 55, Immature Granulocytes Percent 0, Lymphs Percent 25, Mono Percent 11, Eosinophils Percent 9, Basophils Percent 1, Neutrophils Abs 3.2, Immature Granulocytes 0.0, Lymphs Abs, Monocytes Abs 0.6, Basophils Absolute 0.1. Troponin <0.04 (x2), TSH 3rd: 0.709. Phosphorus 3.5, (1721): Total CK 128, CK-MB 1.6, CKMB Index 1.2, D-Dimer Quantitative <0.19. proBNP 165. Magnesium: 1.7. CRP: <2.90 10OCT2020: GFR: 73, Glucose 100, BUN 27, Creatinine 1.11, Sodium 139, Potassium 3.6, Chloride 105, CO2 28.0, Anion Gap 10, Calcium 8.4, Total Protein 6.2, Albumin 3.5, Globulin 2.7, AST 21, Alkaline Phosphatase 51, Total Bilirubin 0.7, ALT 28, HgA1C: 6.5, Troponin (0622) <0.04, Respiratory Pathogen Panel (Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human metapneumovirus, Human rhino/entervirus, Influenza Type A, Influenza A Subtype H1-2009, Influenza A Subtype H1, Influenza ASubtype H3, Influenza Type B, Parainfluenza 1, 2, 3, 4, RSV, Bordetella pertussis, Chlamydophila pneumoniae, and mycoplasma pneumoniae): Negative. Covid Qual PCR negative. ' (Site from DM).	Whitney West (b) (4)	26 Dec 2020 22:17:47
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information on BLOOD Work up is available. Update eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 05:08:33

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, please ensure that this blood work up is recorded in the ConProc eCRF. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:56:22
Query 'Per DM CLR - RQ: Site's response noted. However, please ensure that this blood work up is recorded in the ConProc eCRF. Update eCRF as appropriate.	Kayla Flege (b) (4)	23 Nov 2020 20:03:29
' answered with 'Left message for patient to return call for more information. Will update when patient calls back.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR - RQ: Site's response noted. However, please ensure that this blood work up is recorded in the ConProc eCRF. Update eCRF as appropriate.	(b) (4), (b) (6)	23 Nov 2020 08:50:37
' (Site from DM).		
User closed query 'Per DM CLR: SAE Narrative = HE STATES CARDIAC ENZYMES WERE NORMAL. However, please confirm if this needs to be recorded in the ConProc eCRF. If yes, please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		23 Nov 2020 08:50:37
Query 'Per DM CLR: SAE Narrative = HE STATES CARDIAC ENZYMES WERE NORMAL. However,	Kayla Flege (b) (4)	02 Nov 2020 21:31:31
please confirm if this needs to be recorded in the ConProc eCRF. If yes, please review and ensure that this is captured in the appropriate eCRF. ' answered with 'There were no procedures. Only lab drawn.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: SAE Narrative = HE STATES CARDIAC ENZYMES WERE NORMAL. However, please confirm if this needs to be recorded in the ConProc eCRF. If yes, please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 06:28:14
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?If not done, please state so.' (Site from Safety).		29 Oct 2020 16:48:30

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?If not done, please state so.' answered with 'not done' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 20:16:06
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?If not done, please state so.' (Site from Safety).		23 Oct 2020 19:14:39
User signature succeeded.	Adam Brosz (b) (4)	15 Oct 2020 17:36:59
User entered 'States on 14OCT2020 that he started with mild chest pain on Wednesday 07OCT2020 he woke up with mild chest pain, diaphoresis, and some nausea. He states by Friday, 09OCT2020 the chest pain was worsening and he went to the ER. He was then admitted to the Hospital for a 24 hour observation to R/O Acute Coronary Syndrome, and Pericarditis. Diagnosis from Hospital was Chest Wall Pain. He states cardiac enzymes were normal and he was discharged from the hospital on 10OCT2020. He then saw his PCP on 14OCT2020 due to continued chest pain. PCP states this is intermittent chest wall pain that is worsening and patient was given a script for Hydrocodone/APAP 5/325 mg and Cholchicine 0.6mg.'	Andrea Clement (b) (4) (b) (4)	15 Oct 2020 16:40:21

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Folder: Adverse Events

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

Audit	User	Time (GMT)
User entered 'I'	System	15 Oct 2020 16:40:21

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Folder: Adverse Events

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

Audit	User	Time (GMT)
User entered 'I'	System	15 Oct 2020 16:40:21

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
User entered '0'	System	15 Oct 2020 16:40:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:12:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 09:36:27
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' ' answered with 'no covid per patient' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 23:59:01
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 16:17:46
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 20:56:26
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'yes patient was evaluated for COVID-19 Infection.' (Site from DM).	Kayla Flege (b) (4)	14 Dec 2020 22:22:17
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 23:57:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4)	15 Nov 2020 20:36:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Nov 2020 20:36:48
Data point term sent to Coder	System	15 Nov 2020 20:36:09
User entered 'Cough'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

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Folder: Adverse Events

Form: Adverse Events (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:12:48
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

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Folder: Adverse Events

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

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Folder: Adverse Events

Form: Adverse Events (2)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '05 Nov 2020'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

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Folder: Adverse Events

Form: Adverse Events (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
User entered empty.	System	15 Nov 2020 20:35:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 09:35:55
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'Updated. ' (Site from DM).	Whitney West (b) (4)	20 Jan 2021 00:39:58
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Jan 2021 00:39:46
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	20 Jan 2021 00:39:46
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Jan 2021 00:39:29
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:54:45
User entered 'Yes (Y)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:13:01
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Apr 2021 21:42:40
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	01 Apr 2021 21:42:40
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	01 Apr 2021 21:42:08
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	20 Jan 2021 00:39:35
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	20 Jan 2021 00:39:35
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	20 Jan 2021 00:39:29
User entered '13 Nov 2020' reason for change: New Information	Whitney West (b) (4)	20 Jan 2021 00:39:29
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
User entered empty.	System	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Grade 1/Mild (Grade 1/Mild)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:13:14
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Not Related (NOT RELATED)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Not Related (NOT RELATED)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'None (NONE)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '1'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 21:42:40
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 21:42:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Whitney West (b) (4)	20 Jan 2021 00:39:35
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:13:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
User entered '0'	System	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32
User entered '1'	System	15 Nov 2020 20:35:45

US3272085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Acid-base disorders, HLT: Metabolic acidoses (excl diabetic acidoses), PT: Lactic acidosis, LLT: Lactic acidosis - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 18:04:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 18:04:42
Data point term sent to Coder	System	06 Jan 2021 18:03:48
User entered 'Lactic acidosis'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '31 Dec 2020'	Whitney West (b) (4)	06 Jan 2021 18:03:34

US3272085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
User entered empty.	System	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
Signature has been broken.		15 Apr 2021 21:06:42
User entered 'No (N)' reason for change: New Information		15 Apr 2021 21:06:42
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	01 Apr 2021 21:40:15
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Jan 2021 00:43:19
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	20 Jan 2021 00:43:19
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Jan 2021 00:42:59
User entered 'Yes (Y)'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
Signature has been broken.		15 Apr 2021 21:06:42
User entered '07 Jan 2021' reason for change: New Information		15 Apr 2021 21:06:42
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Apr 2021 21:40:15
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	01 Apr 2021 21:40:15
User entered empty; reason for change New Information	(b) (4), (b) (6)	01 Apr 2021 21:40:15
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	01 Apr 2021 21:34:07
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	20 Jan 2021 00:43:19
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	20 Jan 2021 00:43:19
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	20 Jan 2021 00:42:59
User entered '07 Jan 2021' reason for change: New Information	Whitney West (b) (4)	20 Jan 2021 00:42:59
User entered empty.	Whitney West (b) (4)	06 Jan 2021 18:03:34

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
User entered empty.	System	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
Signature has been broken.		19 Apr 2021 16:10:48
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error		19 Apr 2021 16:10:48
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4) (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Whitney West (b) (4)	06 Jan 2021 18:03:34

US3272085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	06 Jan 2021 18:03:34

US3272085

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	08 Jan 2021 11:52:41
User closed query 'Per CDM RQ: Response noted however, 'Requires inpatient or prolongation of existing Hospitalization "not checked", data for Hospital Admission/Hospital Discharge dates and Admitted to ICU should be 'blank'? Please review/update accordingly else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:35:18
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'Corrected.' (Site from System).	Whitney West (b) (4)	07 Jan 2021 14:01:32
Query 'Per CDM RQ: Response noted however, 'Requires inpatient or prolongation of existing Hospitalization "not checked", data for Hospital Admission/Hospital Discharge dates and Admitted to ICU should be 'blank'? Please review/update accordingly else clarify. Thank you' answered with 'Updated for resolution.' (Site from DM).	Whitney West (b) (4)	07 Jan 2021 14:01:23
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	07 Jan 2021 14:00:37
User opened query 'Per CDM RQ: Response noted however, 'Requires inpatient or prolongation of existing Hospitalization "not checked", data for Hospital Admission/Hospital Discharge dates and Admitted to ICU should be 'blank'? Please review/update accordingly else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 09:03:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	07 Jan 2021 09:00:24
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'He was not inpatient. He was in observation. ' (Site from System).	Whitney West (b) (4)	06 Jan 2021 18:04:01
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	06 Jan 2021 18:03:34
User entered '0'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty; reason for change Per Query Resolution	Whitney West (b) (4)	07 Jan 2021 14:00:37
User entered '31 Dec 2020'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty; reason for change Per Query Resolution	Whitney West (b) (4)	07 Jan 2021 14:00:37
User entered '02 Jan 2021'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty; reason for change Per Query Resolution	Whitney West (b) (4)	07 Jan 2021 14:01:51
User entered 'No (N)'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	06 Jan 2021 18:03:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 14:10:40
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Added ConMed.' (Site from DM).	Whitney West (b) (4)	18 Feb 2021 22:44:22
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 12:46:07
User entered 'I'	Whitney West (b) (4)	06 Jan 2021 18:03:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
Signature has been broken.		15 Apr 2021 21:06:42
User entered '1' reason for change: Per Query Resolution		15 Apr 2021 21:06:42
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 11:20:24
User entered '0' reason for change: Per Query Resolution	Whitney West (b) (4)	18 Feb 2021 22:46:05
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'EEG is diagnostic procedure. Will update.' (Site from DM).	Whitney West (b) (4)	18 Feb 2021 22:45:57
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 12:46:00
User entered '1'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
Signature has been broken.		15 Apr 2021 21:06:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information		15 Apr 2021 21:06:42
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	01 Apr 2021 21:34:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Whitney West (b) (4)	20 Jan 2021 00:43:19
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
DataPoint Verified.		29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: Narrative indicates that subject had "WORKED UP FOR SEPSIS, NEGATIVE PROCALCITONIN AND X-RAY." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:38:13
Query 'Per DM CLR: Narrative indicates that subject had "WORKED UP FOR SEPSIS, NEGATIVE PROCALCITONIN AND X-RAY." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:46:44
User opened query 'Per DM CLR: Narrative indicates that subject had "WORKED UP FOR SEPSIS, NEGATIVE PROCALCITONIN AND X-RAY." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 04:21:09
User closed query 'Per DM CLR: SAE Narrative = HE WAS WORKED UP FOR SEPSIS, HAD NEGATIVE PROCALCITONIN AND X-RAY. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		25 Feb 2021 18:46:10
User closed query 'Per DM CLR: SAE Narrative = HE WAS GIVEN CEFEPIME 1 GRAM Q6. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		19 Feb 2021 14:11:34

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = HE WAS WORKED UP FOR SEPSIS, HAD NEGATIVE PROCALCITONIN AND X-RAY. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'These are diagnostic. Told above, not to include these. ' (Site from DM).	Whitney West (b) (4)	18 Feb 2021 22:46:31
Query 'Per DM CLR: SAE Narrative = HE WAS GIVEN CEFEPIME 1 GRAM Q6. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated. ' (Site from DM).	Whitney West (b) (4)	18 Feb 2021 22:46:13
User opened query 'Per DM CLR: SAE Narrative = HE WAS GIVEN CEFEPIME 1 GRAM Q6. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 12:45:52
User opened query 'Per DM CLR: SAE Narrative = HE WAS WORKED UP FOR SEPSIS, HAD NEGATIVE PROCALCITONIN AND X-RAY. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		24 Jan 2021 12:45:44

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT HAD ACCOMPANIED HIS WIFE TO THE ED FOR A MEDICAL EVENT FOR HER WHEN HE HAD A SYNCOPAL EPISODE AND WAS ADMITTED 31DEC2020. He was worked up for sepsis, had negative procalcitonin and x-ray. LABS WERE DRAWN AND HE WAS DIAGNOSED WITH LACTIC ACIDOSIS. He was given cefepime 1 gram q6 FOR A POTENTIAL DIAGNOSIS OF SEPSIS WHICH WAS EVENTUALLY RULED OUT AND THE ANTIBIOTICS WERE DISCONTINUED. He was referred to neurology and started on levetiracetam 500 mg PO BID for potential seizure activity. HE PRESENTED TO HIS PCP FOR FOLLOW-UP WHERE IT WAS SUSPECTED THAT HIS METFORMIN MAY HAVE INDUCED THE LACTIC ACIDOSIS AND WAS DISCONTINUED. HE REPORTED THE INCIDENT 06DEC2021. Lactic acid: 01JAN2021: 4.6 at 0543, 3.5 at 0800, 0.9 at 1246. 02JAN2021: 1.7 Procalcitonin: 0.5 UA- trace protein, glucose, rare mucous. No culture indicated. CXR negative. 01JAN2021: Influenza A, B, RSV, COVID1-9 negative. Blood cultures at day 2 and 5 negative.' reason for change: New Information	Whitney West (b) (4)	13 Jan 2021 23:35:09
User entered 'Participant had accompanied his wife to the ED for a medical event for her when he had a syncopal episode and was admitted to the emergency department for observation on 31DEC2020. Labs were drawn and he was diagnosed with lactic acidosis. He was given cefepime q6 while in observation for a potential diagnosis of sepsis which was eventually ruled out and the antibiotics were discontinued. He was sent home without further follow-up on 02JAN2021.	Whitney West (b) (4)	06 Jan 2021 18:03:34

He presented to his PCP for follow-up where it was suspected that his Metformin may have induced the lactic acidosis and was discontinued. He reported the incident 06DEC2021.'

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
User entered '0'	System	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
User entered '1'	System	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:17:36
User entered '0'	System	06 Jan 2021 18:03:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:17
User entered	System	29 Apr 2021 20:58:13
'USA-US070-2021-mRNA-1273-P301000011'	(b) (4), (b) (6)	29 Apr 2021 20:58:13
DataPoint Un-verified.		29 Apr 2021 20:58:13
User entered 'New' reason for change: Data Entry Error		29 Apr 2021 20:58:13
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User entered empty.	(b) (4), (b) (6)	27 Apr 2021 23:56:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User closed query 'please verify hospitalization of 1-2Jan2021 for syncopal episode' (Site from CRA).		29 Apr 2021 20:17:46
Query 'please verify hospitalization of 1-2Jan2021 for syncopal episode' answered with 'hospitalization added' (Site from CRA).		29 Apr 2021 19:19:00
User opened query 'please verify hospitalization of 1-2Jan2021 for syncopal episode' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:48:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 21:28:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 21:28:12
Data point term sent to Coder	System	13 Jan 2021 21:27:54
User entered 'Syncope'	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	13 Jan 2021 23:35:33
User entered '31 Dec 2020' reason for change: Data Entry Error	Whitney West (b) (4)	13 Jan 2021 23:35:33
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	13 Jan 2021 21:27:42
User entered '31 Dec 2021'	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	13 Jan 2021 23:35:33
User entered '31 Dec 2020' reason for change: Data Entry Error	Whitney West (b) (4)	13 Jan 2021 23:35:33
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	13 Jan 2021 21:27:42
User entered '31 Dec 2021'	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
Signature has been broken.		29 Apr 2021 19:20:41
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error		29 Apr 2021 19:20:41
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	Whitney West (b) (4) (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).	System	29 Apr 2021 19:19:58
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 19:19:58
User entered 'Yes (Y)' reason for change: Data Entry Error		29 Apr 2021 19:19:58
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	29 Apr 2021 19:19:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
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). DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 06:33:01
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 'corrected' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		29 Apr 2021 19:19:17
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		29 Apr 2021 19:19:17
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). Signature has been broken.	System	29 Apr 2021 19:19:17
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 19:19:17
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	29 Apr 2021 19:18:49
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4) (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
Signature has been broken.		29 Apr 2021 19:18:49
User entered '01 Jan 2021' reason for change: Data Entry Error		29 Apr 2021 19:18:49
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
Signature has been broken.		29 Apr 2021 19:18:49
User entered '02 Jan 2021' reason for change: Data Entry Error		29 Apr 2021 19:18:49
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	13 Mar 2021 01:54:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Feb 2021 22:47:57
User entered '1' reason for change: Per Query Resolution	Whitney West (b) (4)	18 Feb 2021 22:47:57
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Feb 2021 22:47:05
User entered '0'	Whitney West (b) (4)	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Mar 2021 01:54:25
User entered '0'	Whitney West (b) (4)	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 14:12:32
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Updated- diagnostic removed. ' (Site from DM).	Whitney West (b) (4)	18 Feb 2021 22:48:16
User entered '0' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 22:47:05
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 12:46:21
User entered '1'	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	13 Jan 2021 21:27:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 20:18:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 19:19:58
User entered '0'	System	13 Jan 2021 21:27:42

US3272085

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered 'I'	System	13 Jan 2021 21:27:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:00:39
Query 'please add albuterol hfa 500ng BID start date 2jan21 per source' canceled (Site from CRA).		30 Apr 2021 16:48:19
User opened query 'please add albuterol hfa 500ng BID start date 2jan21 per source' (Site from CRA).		26 Apr 2021 17:06:27
DataPoint Verified.		26 Apr 2021 16:33:19
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:40:24

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 12:44:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 12:44:11
Data point term sent to Coder	System	10 Aug 2020 12:43:51
User entered 'Metformin'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 13:57:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 13:57:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 13:57:03
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 12:43:35
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:43:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Diabetes'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	03 May 2021 16:59:22
Signature has been broken.		30 Apr 2021 21:32:51
DataPoint Verified.		30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '1000'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:43:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:43:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
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)	13 Aug 2020 19:43:18
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 'required per protocol' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:57:00
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	10 Aug 2020 12:43:35
User entered 'un UNK 2007'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	06 Jan 2021 18:04:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Jan 2021 18:04:47
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Jan 2021 18:04:38
User entered '06 Jan 2021' reason for change: New Information	Whitney West (b) (4)	06 Jan 2021 18:04:38
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:43:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:43:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:43:35

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:43:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 23:54:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 23:54:45
Data point term sent to Coder Coding entries removed.	System	21 Sep 2020 23:53:54
	(b) (4), (b) (6)	21 Sep 2020 23:53:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 12:46:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 12:46:11
Data point term sent to Coder	System	10 Aug 2020 12:45:53
User entered 'Meloxicam'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per CDM: Please update and provide location of 'OSTEOARTHRITIS' (e.g. Knees, Elbows, Hips, etc.). Please ensure that there is a corresponding MH/AE record that match the updated indication. Please update applicable details as appropriate or provide further clarification.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:14:36
Query 'Per CDM: Please update and provide location of 'OSTEOARTHRITIS' (e.g. Knees, Elbows, Hips, etc.). Please ensure that there is a corresponding MH/AE record that match the updated indication. Please update applicable details as appropriate or provide further clarification.' answered with 'all over body' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 22:51:50
User opened query 'Per CDM: Please update and provide location of 'OSTEOARTHRITIS' (e.g. Knees, Elbows, Hips, etc.). Please ensure that there is a corresponding MH/AE record that match the updated indication. Please update applicable details as appropriate or provide further clarification.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 22:01:15
User closed query 'Per DM CLR: Please review Indication and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, etc.). Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:46:10
Query 'Per DM CLR: Please review Indication and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, etc.). Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:53:46
User entered 'osteoARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 23:53:07

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review Indication and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, etc.). Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 06:06:25
User entered 'Generalized Arthritis'		10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '15'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
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)	13 Aug 2020 19:41:55
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 'required per protocol' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:57:12
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	10 Aug 2020 12:45:37
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:45:37

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:48:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:48:17
Data point term sent to Coder	System	10 Aug 2020 12:47:53
User entered 'Losartan'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Hypertension'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '50'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
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)	13 Aug 2020 19:41:56
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 'required per protocol' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:57:17
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	10 Aug 2020 12:46:58
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:46:58

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: THIAZOLIDINEDIONES, PRODUCT: PIOGLITAZONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 17:39:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 17:39:14
Data point term sent to Coder	System	10 Aug 2020 12:48:54
User entered 'Pioglitazone'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Type 2 diabetes'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '30'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
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)	13 Aug 2020 19:41:57
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 'required per protocol' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:57:23
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	10 Aug 2020 12:48:26
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:48:26

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
Query 'please verify entry deleted per CM log in source' canceled (Site from CRA).		26 Apr 2021 16:36:41
User opened query 'please verify entry deleted per CM log in source' (Site from CRA).		26 Apr 2021 16:35:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
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)	10 Aug 2020 12:51:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:51:54
Data point term sent to Coder	System	10 Aug 2020 12:49:54
User entered 'Atorvastatin'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '10'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'every other day (QOD)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:03:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
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)	13 Aug 2020 19:41:58
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 'required per protocol' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:57:28
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 12:49:25
User entered 'un UNK 2012'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

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

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 16:03:54
User entered '1'	System	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:49:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:53:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:53:12
Data point term sent to Coder	System	10 Aug 2020 12:51:55
User entered 'Hydrochlorothiazide'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Hypertension'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '12.5'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
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)	13 Aug 2020 19:41:59
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 'required per protocol' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:57:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 12:51:14
User entered 'un UNK 2019'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:51:14

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 01:38:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 01:38:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN LOW - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 23:55:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 23:55:46
Data point term sent to Coder	System	21 Sep 2020 23:54:57
Coding entries removed.	(b) (4), (b) (6)	21 Sep 2020 23:54:19
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN LOW - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 15:09:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 15:09:47

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:49:19
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 Aug 2020 18:49:19
Data point term sent to Coder	System	10 Aug 2020 12:54:59
User entered 'Low dose aspirin'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 23:54:33
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: Please review Indication and please update to add/include the medical condition that this medication was used to prevent. Please also update Prophylaxis to YES accordingly. Please update applicable details as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 19:03:37
Query 'Per DM CLR: Please review Indication and please update to add/include the medical condition that this medication was used to prevent. Please also update Prophylaxis to YES accordingly. Please update applicable details as appropriate or provide clarification.	(b) (4), (b) (6)	21 Sep 2020 23:54:27
' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:54:19
User entered 'cardiac prophylaxis' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 06:05:57
User opened query 'Per DM CLR: Please review Indication and please update to add/include the medical condition that this medication was used to prevent. Please also update Prophylaxis to YES accordingly. Please update applicable details as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	10 Aug 2020 12:54:27
User entered 'Preventative'	(b) (4), (b) (6)	

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '81'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'UN UNK 2013' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:13:32
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)	13 Aug 2020 19:42:00
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 'required per protocol' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:57:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 12:54:27
User entered 'un UNK 2015'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:54:27

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: NEBIVOLOL HYDROCHLORIDE, PRODUCTSYNONYM: BYSTOLIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 23:56:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 23:56:47
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	21 Sep 2020 23:55:57 21 Sep 2020 23:55:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: NEBIVOLOL HYDROCHLORIDE, PRODUCTSYNONYM: BYSTOLIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 12:58:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 12:58:21
Data point term sent to Coder User entered 'Bystolic'	System (b) (4), (b) (6)	10 Aug 2020 12:57:01 10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
Query 'Per CDM: There is no corresponding Medical History record that match this condition. Kindly review and update as appropriately.' canceled (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:51:03
User opened query 'Per CDM: There is no corresponding Medical History record that match this condition. Kindly review and update as appropriately.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:50:46
User closed query 'Per DM CLR: Indication of Cardiac Prophylaxis was noted, however, there is a recorded MH condition of Hypertension that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:50:46
Query 'Per DM CLR: Indication of Cardiac Prophylaxis was noted, however, there is a recorded MH condition of Hypertension that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:55:41
User entered 'hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 23:55:35
User opened query 'Per DM CLR: Indication of Cardiac Prophylaxis was noted, however, there is a recorded MH condition of Hypertension that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 06:04:39
User entered 'Cardiac Prophylaxis'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '5'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
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)	13 Aug 2020 19:42:01
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 'required per protocol' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:57:43
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	10 Aug 2020 12:56:59
User entered 'un UNK 2013'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:56:59

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
Query 'please verify entry deleted per CM log' canceled (Site from CRA).		26 Apr 2021 16:37:08
User opened query 'please verify entry deleted per CM log' (Site from CRA).		26 Apr 2021 16:36:06
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 23:57:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 23:57:49
Data point term sent to Coder	System	21 Sep 2020 23:57:06
Coding entries removed.	(b) (4), (b) (6)	21 Sep 2020 23:56:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 17:35:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 17:35:25
Data point term sent to Coder	System	10 Aug 2020 12:58:01
User entered 'Omeprazole'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: Indication of Preventative was noted, however, there is a recorded MH condition of Gastroesophageal Reflux Disease that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, update to add/include the medical condition this medication was used to prevent. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:52:32
Query 'Per DM CLR: Indication of Preventative was noted, however, there is a recorded MH condition of Gastroesophageal Reflux Disease that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, update to add/include the medical condition this medication was used to prevent. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:56:22
User entered 'gastroesophageal reflux disease' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 23:56:16
User opened query 'Per DM CLR: Indication of Preventative was noted, however, there is a recorded MH condition of Gastroesophageal Reflux Disease that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, update to add/include the medical condition this medication was used to prevent. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 06:06:47
User entered 'Preventative'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '40' reason for change: New Information	(b) (4), (b) (6)	10 Aug 2020 13:01:04
User entered '1'		10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'twice daily (BID)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:04:12
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
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)	13 Aug 2020 19:42:02
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 'required per protocol' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:57:48
User entered 'UN UNK 2009' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 13:01:04
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	10 Aug 2020 12:57:55
User entered 'un UNK 2015'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 16:04:12
User entered '1'	System	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 12:57:55

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
Query 'please verify entry deleted per CM log' canceled (Site from CRA).		26 Apr 2021 16:37:33
User opened query 'please verify entry deleted per CM log' (Site from CRA).		26 Apr 2021 16:36:13
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: BILE ACID SEQUESTRANTS, PRODUCT: COLESTIPOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 21:32:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 21:32:43
Data point term sent to Coder	System	15 Oct 2020 16:07:19
Coding entries removed.	Ashley Bell (b) (4)	15 Oct 2020 16:06:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: BILE ACID SEQUESTRANTS, PRODUCT: COLESTIPOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:57:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:57:49
Data point term sent to Coder	System	21 Sep 2020 23:57:06
Coding entries removed.	(b) (4), (b) (6)	21 Sep 2020 23:56:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: BILE ACID SEQUESTRANTS, PRODUCT: COLESTIPOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:41:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:41:12
Data point term sent to Coder	System	10 Aug 2020 13:03:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	10 Aug 2020 13:02:06
User entered 'Colestipol'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: Indication of Preventative was noted, however, there is a recorded MH condition of Hypercholesterolemia that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, update to add/include the medical condition this medication was used to prevent. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:52:01
User entered 'Diarrhea' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:06:36
Query 'Per DM CLR: Indication of Preventative was noted, however, there is a recorded MH condition of Hypercholesterolemia that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, update to add/include the medical condition this medication was used to prevent. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 23:57:24
User entered 'hypercholesterolemia' reason for change: Data Entry Error		21 Sep 2020 23:56:46
User opened query 'Per DM CLR: Indication of Preventative was noted, however, there is a recorded MH condition of Hypercholesterolemia that match this medication. Please verify if this was given as treatment for the MH condition and update accordingly. Otherwise, update to add/include the medical condition this medication was used to prevent. ' (Site from DM).		17 Sep 2020 06:05:11
User entered 'Preventative'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'I'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'g (g)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:05:27
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'as needed (PRN)' reason for change:	Ashley Bell (b) (4)	15 Oct 2020 16:05:27
Data Entry Error		
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 13:02:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 13:02:21
User entered 'Oral (ORAL)' reason for change: New Information	(b) (4), (b) (6)	10 Aug 2020 13:02:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 13:01:46
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
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)	13 Aug 2020 19:42:07
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 'required per protocol' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 13:57:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 13:01:46
User entered 'un UNK 2015'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:05:27
User entered '1'	System	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:05:27
User entered '1'	System	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:05:27
User entered '804 (804)'	System	10 Aug 2020 13:01:46

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:31:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:31:27
Data point term sent to Coder	System	15 Oct 2020 16:30:11
Coding entries removed.	Ashley Bell (b) (4)	15 Oct 2020 16:30:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:15:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:15:27
Data point term sent to Coder	System	15 Oct 2020 16:14:36
User entered 'hydrocodone/apap'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'WORSENING intermittent CHEST WALL PAIN' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:30:05
User entered 'worsening chest wall pain'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '5/325'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	15 Oct 2020 16:14:32
User entered 'Other (OTHER)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:14:32
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	15 Oct 2020 16:14:21
User entered 'mg (mg)'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '1-2 tablets max 10/650mg'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'other (OTHER)'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'every 4-6 as needed'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Oral (ORAL)'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '14 Oct 2020'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Ashley Bell (b) (4)	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:14:21

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 21:26:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 21:26:08
Data point term sent to Coder	System	15 Oct 2020 16:31:15
Coding entries removed.	Ashley Bell (b) (4)	15 Oct 2020 16:30:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:28:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:28:42
Data point term sent to Coder	System	15 Oct 2020 16:15:38
User entered 'cholchicine'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'WORSENING intermittent CHEST WALL PAIN' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Oct 2020 16:30:18
User entered 'worsening chest wall pain'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0.6'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'mg (mg)'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'twice daily (BID)'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Oral (ORAL)'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '14 Oct 2020'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Ashley Bell (b) (4)	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 16:15:25

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: This Conmed is given for the AE#4 SYNCOPE. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 08:56:12
Query 'Per DM CLR: This Conmed is given for the AE#4 SYNCOPE. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:53:23
User opened query 'Per DM CLR: This Conmed is given for the AE#4 SYNCOPE. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:06:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 22:13:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 22:13:01
Data point term sent to Coder	System	13 Jan 2021 21:30:57
User entered 'Levetiracetam'	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Syncope'	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '500'	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'mg (mg)'	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'twice daily (BID)'	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Oral (ORAL)'	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:59:09
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'updated' (Site from DM)	(b) (4), (b) (6)	15 Feb 2021 23:08:32
User entered '31 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 23:07:23
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 08:38:20
User entered '02 Jan 2021'	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:59:17
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data is correct as entered' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 23:08:46
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 08:38:38
User entered 'Yes (Y)'	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Whitney West (b) (4)	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Jan 2021 21:30:09

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 13:15:00
DataPoint Verified.		30 Apr 2021 13:11:34
User closed query 'please add entry to CM log' (Site from CRA).		30 Apr 2021 13:11:16
Query 'please add entry to CM log' answered with 'updated' (Site from CRA).		29 Apr 2021 21:28:22
User opened query 'please add entry to CM log' (Site from CRA).		26 Apr 2021 16:39:01
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 22:44:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 22:44:05
Data point term sent to Coder	System	18 Feb 2021 22:40:25
User entered 'Cefepime'	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 13:21:04
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 13:22:24
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Lactic acidosis'	Whitney West (b) (4) (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'I'	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'g (g)'	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'four times daily (QID)'	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	18 Feb 2021 22:42:54
User entered '31 Dec 2020' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 22:42:54
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	18 Feb 2021 22:40:03
User entered empty.	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 13:16:41
DataPoint Verified.		30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '0'	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 13:16:10
DataPoint Verified.		30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 22:42:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 22:42:54
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 22:42:54
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 22:40:03
User entered empty.	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 13:15:44
DataPoint Verified.		30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '01 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 22:42:54
User entered empty.	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 13:15:17
DataPoint Verified.		30 Apr 2021 13:11:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 22:40:03

US3272085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:25:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Feb 2021 22:40:03

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:25:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:00:39
Query 'please verify EKG per 1Jan21 ED note' canceled (Site from CRA).		30 Apr 2021 16:50:03
Query 'please verify MRI-brain per 2Jan21 source' canceled (Site from CRA).		30 Apr 2021 16:50:01
User opened query 'please verify MRI-brain per 2Jan21 source' (Site from CRA).		26 Apr 2021 17:14:55
User opened query 'please verify EKG per 1Jan21 ED note' (Site from CRA).		26 Apr 2021 17:13:22
DataPoint Verified.		26 Apr 2021 16:31:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	13 Jan 2021 21:24:18
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 13:56:28

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Jan 2021 22:13:59
User entered '04 Jan 2021' reason for change: New Information	Whitney West (b) (4)	13 Jan 2021 22:13:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Jan 2021 22:13:43
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 22:13:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 22:13:43
User entered '04 Jan 201' (non-conformant).	Whitney West (b) (4)	13 Jan 2021 22:13:43
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 21:25:30
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:25:30

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:25:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Electroencephalogram'	Whitney West (b) (4)	13 Jan 2021 21:25:30

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 22:13:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 22:13:43
User entered 'Adverse Event (AE)' reason for change: New Information	Whitney West (b) (4)	13 Jan 2021 22:13:43
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 21:25:30
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:25:30

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:25:43

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	Whitney West (b) (4)	13 Jan 2021 21:25:30

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:08
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '31 Dec 2020'	(b) (4), (b) (6)	13 Mar 2021 01:49:41

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:25:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:08
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'work up for sepsis'	(b) (4), (b) (6)	13 Mar 2021 01:49:41

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:08
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Mar 2021 01:49:41

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:25:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:08
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	13 Mar 2021 01:49:41

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:13
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '31 Dec 2020'	(b) (4), (b) (6)	13 Mar 2021 01:50:12

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:25:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:13
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'negative procalcitonin'	(b) (4), (b) (6)	13 Mar 2021 01:50:12

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:13
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Mar 2021 01:50:12

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:25:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:13
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	13 Mar 2021 01:50:12

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:24
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered '31 Dec 2020'	(b) (4), (b) (6)	13 Mar 2021 01:50:29

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:25:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:24
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'x-ray'	(b) (4), (b) (6)	13 Mar 2021 01:50:29

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:24
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Mar 2021 01:50:29

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:25:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:36:24
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 14:53:34
User entered empty.	(b) (4), (b) (6)	13 Mar 2021 01:50:29

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:33
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered '04 Jan 2021'	(b) (4), (b) (6)	15 Apr 2021 21:07:30

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:25:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:33
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Electroencephalogram'	(b) (4), (b) (6)	15 Apr 2021 21:07:30

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:33
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 21:07:30

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:25:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:37:33
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:07:30

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:47:59
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
User entered '01 Jan 2021'	(b) (4), (b) (6)	29 Apr 2021 19:37:55

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:25:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:47:59
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
User entered 'EKG'	(b) (4), (b) (6)	29 Apr 2021 19:37:55

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:47:59
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	29 Apr 2021 19:37:55

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:25:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:47:59
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 19:37:55

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:25:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:48:06
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
User entered '02 Jan 2021'	(b) (4), (b) (6)	29 Apr 2021 19:39:55

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:25:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:48:06
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
User entered 'MRI'	(b) (4), (b) (6)	29 Apr 2021 19:39:55

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:25:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:48:06
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	29 Apr 2021 19:39:55

US3272085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:25:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:48:06
DataPoint Verified.		30 Apr 2021 16:49:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 19:39:55

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 17:31:51
User entered '8'	System	29 Apr 2021 21:18:02
User entered '7'	System	16 Apr 2021 15:47:23
User entered '6'	System	04 Jan 2021 15:07:16
User entered '5'	System	02 Dec 2020 18:03:31
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 17:31:51
User entered '8'	System	29 Apr 2021 21:18:02
User entered '7'	System	16 Apr 2021 15:47:23
User entered '6'	System	04 Jan 2021 15:07:16
User entered '5'	System	02 Dec 2020 18:03:31
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
User entered '15/Oct/2020 20:29'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:25:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:49:09
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 17:31:51
User entered '8'	System	29 Apr 2021 21:18:02
User entered '7'	System	16 Apr 2021 15:47:23
User entered '6'	System	04 Jan 2021 15:07:16
User entered '5'	System	02 Dec 2020 18:03:31
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
User entered '29/Oct/2020 16:50'	System	29 Oct 2020 16:50:28

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:25:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		03 Nov 2020 14:31:10
Un-reviewed for Safety.		29 Oct 2020 16:50:28
User entered '1' reason for change: Data Entry Error		29 Oct 2020 16:50:28
Reviewed for Safety.		29 Oct 2020 16:49:09
User entered '0'		16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 17:31:51
User entered '8'	System	29 Apr 2021 21:18:02
User entered '7'	System	16 Apr 2021 15:47:23
User entered '6'	System	04 Jan 2021 15:07:16
User entered '5'	System	02 Dec 2020 18:03:31
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
User entered '03/Nov/2020 14:31'	System	03 Nov 2020 14:31:40

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:25:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		20 Nov 2020 15:43:13
Un-reviewed for Safety.		03 Nov 2020 14:31:40
User entered '1' reason for change: Obvious Correction		03 Nov 2020 14:31:40
Reviewed for Safety.		03 Nov 2020 14:31:10
User entered '0'		29 Oct 2020 16:50:28

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 17:31:51
User entered '8'	System	29 Apr 2021 21:18:02
User entered '7'	System	16 Apr 2021 15:47:23
User entered '6'	System	04 Jan 2021 15:07:16
User entered '5'	System	02 Dec 2020 18:03:31
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
User entered '20/Nov/2020 15:43'	System	20 Nov 2020 15:43:24

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:25:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		02 Dec 2020 18:03:22
User entered 'I'		20 Nov 2020 15:43:24

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 17:31:51
User entered '8'	System	29 Apr 2021 21:18:02
User entered '7'	System	16 Apr 2021 15:47:23
User entered '6'	System	04 Jan 2021 15:07:16
User entered '5'	System	02 Dec 2020 18:03:31
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
User entered '02/Dec/2020 18:03'	System	02 Dec 2020 18:03:31

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:25:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		04 Jan 2021 15:07:05
User entered 'I'		02 Dec 2020 18:03:31

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 17:31:51
User entered '8'	System	29 Apr 2021 21:18:02
User entered '7'	System	16 Apr 2021 15:47:23
User entered '6'	System	04 Jan 2021 15:07:16
User entered '5'	System	02 Dec 2020 18:03:31
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
User entered '04/Jan/2021 10:07'	System	04 Jan 2021 15:07:16

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:25:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Apr 2021 15:47:07
User entered 'I'		04 Jan 2021 15:07:16

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (5)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 17:31:51
User entered '8'	System	29 Apr 2021 21:18:02
User entered '7'	System	16 Apr 2021 15:47:23
User entered '6'	System	04 Jan 2021 15:07:16
User entered '5'	System	02 Dec 2020 18:03:31
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
User entered '16/Apr/2021 11:47'	System	16 Apr 2021 15:47:23

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:25:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 21:17:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
User entered 'I'		16 Apr 2021 15:47:23

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 17:31:51
User entered '8'	System	29 Apr 2021 21:18:02
User entered '7'	System	16 Apr 2021 15:47:23
User entered '6'	System	04 Jan 2021 15:07:16
User entered '5'	System	02 Dec 2020 18:03:31
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
User entered '29/Apr/2021 16:18'	System	29 Apr 2021 21:18:02

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:25:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:31:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 21:18:02

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'USA-US070-2020-MRNA-1273-P301000006'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Yes (Y)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:29:24
User entered 'No (N)'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Adam'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Brosz'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '2444 W. Faidley Ave'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'Grand Island'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered 'NE'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		16 Oct 2020 00:29:24
User entered '68803'	System	16 Oct 2020 00:29:10

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 17:14:57
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:14:53
Reviewed for Safety.		29 Oct 2020 16:49:09
User entered 'US'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	30 Apr 2021 17:31:51
User entered '8'	System	29 Apr 2021 21:18:02
User entered '7'	System	16 Apr 2021 15:47:23
User entered '6'	System	04 Jan 2021 15:07:16
User entered '5'	System	02 Dec 2020 18:03:31
User entered '4'	System	20 Nov 2020 15:43:24
User entered '3'	System	03 Nov 2020 14:31:40
User entered '2'	System	29 Oct 2020 16:50:28
User entered '1'	System	16 Oct 2020 00:29:32

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
User entered '30/Apr/2021 13:31'	System	30 Apr 2021 17:31:51

US3272085

Folder: SAE USA-US070-2020-MRNA-1273-P301000006

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:25:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	03 May 2021 16:59:22
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 17:31:51

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'USA-US070-2021-MRNA-1273-P301000011'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'Yes (Y)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'No (N)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'No (N)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'Yes (Y)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'No (N)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'No (N)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'No (N)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'Adam'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'Brosz'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered '2444 W. Faidley Ave'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'Grand Island'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'NE'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered '68803'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'US'	System	29 Apr 2021 20:58:35

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 20:58:35

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'USA-US070-2021-MRNA-1273-P301000011'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'Yes (Y)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'No (N)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'No (N)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'Yes (Y)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'No (N)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'No (N)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'No (N)'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'Adam'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'Brosz'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered '2444 W. Faidley Ave'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'Grand Island'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'NE'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered '68803'	System	29 Apr 2021 20:58:13

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'US'	System	29 Apr 2021 20:58:35

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:25:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 20:58:35

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:25:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
User entered '29/Apr/2021 13:58'	System	29 Apr 2021 20:58:35

US3272085

Folder: SAE USA-US070-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:25:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:15:27
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:58:38
User entered 'I'		29 Apr 2021 20:58:35