

US3272377 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:24:46

All time stamps listed in this document are displayed in GMT

US3272377

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

[Participant ID](#)

US3272377

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

US3272377

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

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

Visit date (dd MMM yyyy)	15 OCT 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	SCRN
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US3272377

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Date of Birth (MMM yyyy)	(b) (6)	1972
Age		48
Age Units		YEARS
Age (Derived)		48
Sex	Female	<input type="radio"/>
	Male	<input checked="" type="radio"/>
Ethnicity	Hispanic or Latino	<input type="radio"/>
	Not Hispanic or Latino	<input checked="" type="radio"/>
	Not Reported	<input type="radio"/>
	Unknown	<input type="radio"/>
Race (Check All That Apply)		
White		False
Black		True
Asian		False
American Indian or Alaska Native		False
Native Hawaiian or other Pacific Islander		False
Other		False
If race is Other, specify _____		
Unknown		False
Not reported		False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Apr 2021 15:15:41

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Date of Informed Consent (<i>dd MMM yyyy</i>)	15 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input checked="" type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Apr 2021 15:15:41

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

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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 15:15:41

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
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 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	SINGLE LEVEL CERVICAL SURGICAL FUSION
Start date (dd MMM yyyy)	14 FEB 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	14 FEB 2018
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	FEB 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	SINGLE LEVEL CERVICAL SURGICAL FUSION
Start date (dd MMM yyyy)	14 FEB 2013
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)	14 FEB 2013
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2013
Start Year (derived)	2013
Stop Month and Year (derived)	FEB 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	LUMBAR SINGLE LEVEL SURGICAL FUSION
Start date (dd MMM yyyy)	27 NOV 2012
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)	27 NOV 2012
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2012
Start Year (derived)	2012
Stop Month and Year (derived)	NOV 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	CHRONIC CERVICAL PAIN
Start date (dd MMM yyyy)	11 JUN 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)	JUN 2012
Start Year (derived)	2012
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 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	SEVERE OBESITY
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 (9)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	LUMBAR PAIN
Start date (dd MMM yyyy)	11 JUN 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)	JUN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	SEVERE ALCOHOL USE DISORDER- NOT IN REMISSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	MAJOR DEPRESSIVE DISORDER RECURRENT, SEVERE, WITH PSYCHOTIC FEATURES
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	CHRONIC KIDNEY DISEASE
Start date (dd MMM yyyy)	06 NOV 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	06 NOV 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	HYPOKALEMIA
Start date (dd MMM yyyy)	06 NOV 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Condition	SCHIZOAFFECTIVE DISORDER BIPOLAR TYPE
Start date (dd MMM yyyy)	05 NOV 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	11:57 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 11:57
Height (xxx.x)	179.5 cm
Weight (xxx.x)	130.8 kg
BMI (xxx.x)	40.59559 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 15:15:41

Generated On: 09 Jun 2021 16:24:46

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Apr 2021 15:15:41

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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

TAKES KIDS TO PARK, KIDS GO TO SCHOOL, GOES GROCERY SHOPPING

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Apr 2021 15:15:41

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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)	True
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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

What was the date of randomization? (dd MMM yyyy) 15 OCT 2020

What was the participant's randomization number? 146664

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

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 23:16:42

Generated On: 09 Jun 2021 16:24:46

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)	15 OCT 2020
Time of assessment (00:00-23:59)	11:57 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 11:57
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

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)	15 OCT 2020
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 13:46
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 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 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

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) 15 OCT 2020

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

Treatment Date and Time (derived) 15 OCT 2020 13:13

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 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

12:30 (24 HR)

Collection date and time (derived)

15 OCT 2020 12:30

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:25	15 OCT 2020 12:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp 15 OCT 2020 14:01

PC Open Date & Time 15 OCT 2020 13:33

PC Close Date & Time 15 OCT 2020 16:03

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °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	15 OCT 2020 17:08
PC Open Date & Time	15 OCT 2020 16:58
PC Close Date & Time	16 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 12:37

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 14:39

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 12:00

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

98.5 °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

20 OCT 2020 09:36

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

20 OCT 2020 12:03

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

97.1 °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

21 OCT 2020 13:06

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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

15 OCT 2020 14:01

PC Open Date & Time

15 OCT 2020 13:33

PC Close Date & Time

15 OCT 2020 16:03

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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

15 OCT 2020 17:09

PC Open Date & Time

15 OCT 2020 16:58

PC Close Date & Time

16 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

16 OCT 2020 12:38

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 14:39

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

18 OCT 2020 12:01

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

20 OCT 2020 09:37

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

20 OCT 2020 12:04

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

21 OCT 2020 13:06

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 14:02
PC Open Date & Time	15 OCT 2020 13:33
PC Close Date & Time	15 OCT 2020 16:03

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 17:09
PC Open Date & Time	15 OCT 2020 16:58
PC Close Date & Time	16 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

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 ☒

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EAB) (1725)

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 12:38
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 14:40
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 2102

EAB) (1725)

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

65 of 2102

EAB) (1725)

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 09:37
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

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 ☒

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 13:07
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3272377

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272377

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272377

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272377

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272377

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272377

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272377

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

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

Visit date (dd MMM yyyy)	16 NOV 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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US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

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 NOV 2020
Time of assessment (00:00-23:59)	13:19 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 13:19
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	14:46 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 14:46
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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3272377

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3272377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

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) 16 NOV 2020

What was the treatment time? (00:00-23:59) 14:10 (24 HR)

Treatment Date and Time (derived) 16 NOV 2020 14:10

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

US3272377

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 NOV 2020

Collection time (00:00-23:59)

13:34 (24 HR)

Collection date and time (derived)

16 NOV 2020 13:34

US3272377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Collection date (dd MMM yyyy)			16 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:29	16 NOV 2020 13:29
Nasopharyngeal Swab 2	No		

US3272377

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 NOV 2020 14:46

PC Open Date & Time

16 NOV 2020 14:30

PC Close Date & Time

16 NOV 2020 17:00

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °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	17 NOV 2020 06:04
PC Open Date & Time	16 NOV 2020 17:55
PC Close Date & Time	17 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

101.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 NOV 2020 15:57

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	18 NOV 2020 19:31
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

97.4 °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

21 NOV 2020 12:21

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 NOV 2020 14:47

PC Open Date & Time

16 NOV 2020 14:30

PC Close Date & Time

16 NOV 2020 17:00

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 NOV 2020 06:05

PC Open Date & Time

16 NOV 2020 17:55

PC Close Date & Time

17 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

17 NOV 2020 15:58

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

1

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 NOV 2020 19:32

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

21 NOV 2020 12:20

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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

No ☒

Yes ☐

PC Time stamp	16 NOV 2020 14:48
PC Open Date & Time	16 NOV 2020 14:30
PC Close Date & Time	16 NOV 2020 17:00

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

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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 ☐

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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

No ☒

Yes ☐

PC Time stamp	17 NOV 2020 06:05
PC Open Date & Time	16 NOV 2020 17:55
PC Close Date & Time	17 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☒

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

107 of 2102

EAB) (1725)

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

Yes <input type="checkbox"/>	
PC Time stamp	18 NOV 2020 19:33
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

Yes ☐

PC Time stamp

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

Yes ☐

PC Time stamp

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

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 ☒

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

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
EAB) (1725)

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US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

Yes ☐

PC Time stamp

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3272377

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3272377

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272377

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272377

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272377

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272377

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272377

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

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

Visit date (dd MMM yyyy)	15 DEC 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
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US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 DEC 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	15 DEC 2020 11:15
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)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272377

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 DEC 2020

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

US3272377

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 DEC 2020

Collection time (00:00-23:59)

11:23 (24 HR)

Collection date and time (derived)

15 DEC 2020 11:23

US3272377

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 61

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 11:23:23

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	19 DEC 2020 00:01
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Patient Cloud Close Date & Time	23 DEC 2020 23:59
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US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 103

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

23 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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="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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

27 FEB 2021 15:34:08

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

08 MAR 2021 10:51:42

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 23:01:43

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 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	20 MAR 2021 00:02:38
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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	27 MAR 2021 02:53:37
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 09:44:09

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

10 APR 2021 07:23:15

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 01:41:45

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 21:31:30

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 00:18:02

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 <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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 243

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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="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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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°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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 <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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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="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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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="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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 719

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

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

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

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

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

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

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2022 00:01
Patient Cloud Close Date & Time	16 NOV 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

26 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

[Patient Cloud Open Date & Time](#)

03 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2022 00:01
Patient Cloud Close Date & Time	14 DEC 2022 23:59

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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="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"/>

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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

17 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2022 23:59

US3272377

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:24:46

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		27 FEB 2021 15:34:24

US3272377

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3272377

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272377

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3272377

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272377

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272377

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272377

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272377

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272377

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:24:46

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"/>

US3272377

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:24:46

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3272377

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

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

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

Visit date (dd MMM yyyy)	27 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3272377

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Date of updated informed consent (dd MMM yyyy) 27 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 27 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3272377

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 FEB 2021

Collection time (00:00-23:59)

09:27 (24 HR)

Collection date and time (derived)

27 FEB 2021 09:27

US3272377

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 FEB 2021

Collection time (00:00 - 23:59)

09:26

Collection Date and Time (derived)

27 FEB 2021 09:26

US3272377

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:15:39

Generated On: 09 Jun 2021 16:24:46

AEID	USA-US070-2020-MRNA-1273-P30 1000026
Adverse event	SUICIDAL IDEATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 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)	30 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	30 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:15:39

Generated On: 09 Jun 2021 16:24:46

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	PT HAS HISTORY OF MAJOR DEPRESSIVE DISORDER, RECURRENT, SEVERE, WITH PSYCHOTIC FEATURES. THE SUICIDAL IDEATION IS RESOLVED, BUT NOT THE MENTAL ILLNESS ASSOCIATED.

Narrative

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:15:39

Generated On: 09 Jun 2021 16:24:46

PT WENT TO THE ER ON 21NOV2020 DUE TO SUICIDAL IDEATION. HE WAS ADMITTED TO ACH IMMANUEL MEDICAL CLINIC FOR INPATIENT TREATMENT ON 22NOV2020 DUE TO SUICIDAL IDEATION AND MULTIPLE PSYCHIATRIC DISORDERS AND SUBSTANCE ABUSE THAT HE HAS A HISTORY OF. LAB INCLUDING CBC, CMP, DRUG SCREEN AND ALCOHOL LEVELS WERE PERFORMED ON 21NOV2020 AT THE ER DEPARTMENT (ST. FRANCIS IN GI) BEFORE TRANSFERRING TO OMAHA. DRUG SCREEN WAS POSITIVE FOR OPIATES, AND COCAINE. COVID 19 TEST PERFORMED AND WAS NEG ON 22NOV2020. SEE MEDICAL RECORDS. SEE MEDICAL HISTORY.

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

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

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

Yes ☒

No ☐

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

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

	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 2016
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication SPRING VALLEY - SUPER
VITAMIN B-COMPLEX

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

	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 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"/>

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication FEVER

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 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 checked="" type="radio"/>
	No	<input type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication AMITRIPTYLINE

Prophylaxis Yes ☐
No ☒

Indication SEVERE, MAJOR RECURRENT
DEPRESSION

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication FAMOTIDINE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC LUMBAR PAIN,
CHRONIC CERVICAL PAIN

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

	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)	18 NOV 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication ARIPIPRAZOLE

Prophylaxis Yes ☒
No ☐

Indication SUICIDAL IDEATION

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication NORTRIPTYLINE

Prophylaxis Yes ☒
No ☐

Indication SUICIDAL IDEATION

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC LUMBAR PAIN,
CHRONIC CERVICAL PAIN

Dose per administration 10/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC NECK AND CHRONIC
BACK PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

Name of Medication BUPROPION 24 HOUR

Prophylaxis Yes ☐
No ☒

Indication MAJOR DEPRESSIVE DISORDER

Dose per administration 150

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) 09 Apr 2021 15:15:40

Generated On: 09 Jun 2021 16:24:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3272377

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 15:15:41

Generated On: 09 Jun 2021 16:24:46

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3272377

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:24:46

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

US3272377

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:24:46

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 ☐

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

SAEID	USA-US070-2020-MRNA-1273-P301000026
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)	6

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

SAEID	USA-US070-2020-MRNA-1273-P301000026
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)	6
Date of submission (Pre-filled from custom function)	30/NOV/2020 12:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

SAEID	USA-US070-2020-MRNA-1273-P301000026
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)	6
Date of submission (Pre-filled from custom function)	01/DEC/2020 09:34
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

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

SAEID	USA-US070-2020-MRNA-1273-P301000026
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)	6
Date of submission (Pre-filled from custom function)	15/DEC/2020 08:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

SAEID	USA-US070-2020-MRNA-1273-P301000026
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)	6
Date of submission (Pre-filled from custom function)	15/DEC/2020 10:55
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

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

SAEID	USA-US070-2020-MRNA-1273-P301000026
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)	6
Date of submission (Pre-filled from custom function)	28/DEC/2020 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

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Apr 2021 23:16:42

Generated On: 09 Jun 2021 16:24:46

SAEID	USA-US070-2020-MRNA-1273-P301000026
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)	6
Date of submission (Pre-filled from custom function)	22/FEB/2021 13:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3272377 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272377

Form: Participant Creation

Generated On: 09 Jun 2021 16:24:46

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'US3272377'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 17:44:21

US3272377

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 18:58:02

US3272377

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '15 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 17:44:22

US3272377

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Oct 2020 18:58:02

US3272377

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'SCRN'	System	15 Oct 2020 18:58:02

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered (b) (6) 1972'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 17:44:23

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '48'	(b) (4), (b) (6)	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'YEARS'	System	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '48'	System	15 Oct 2020 18:57:17

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Male (M)'	(b) (4), (b) (6)	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:24:46

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 18:58:33

US3272377

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:46

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 18:57:17

US3272377

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Oct 2020'	System	15 Oct 2020 18:57:17

US3272377

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2020'	System	15 Oct 2020 18:57:17

US3272377

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 18:57:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 18:57:22
User entered 'Amendment 4 (4)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 18:57:22
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 18:57:17
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 18:57:17

US3272377

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 18:57:17

US3272377

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 18:57:17

US3272377

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 18:57:17

US3272377

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 18:57:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 18:57:17

US3272377

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	15 Oct 2020 18:57:45
User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System).	System	15 Oct 2020 18:57:17
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 17:44:22

US3272377

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:24:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'I'	System	15 Oct 2020 18:58:46

US3272377

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 18:58:46

US3272377

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:24:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 22:59:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 22:59:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 22:59:23
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 22:58:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 22:58:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 22:41:51

US3272377

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 23:07:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 23:07:30
Data point term sent to Coder	System	15 Oct 2020 23:06:23
User entered 'Hypertension'	(b) (4), (b) (6)	15 Oct 2020 23:05:49

US3272377

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'UN UNK 2016'	(b) (4), (b) (6)	15 Oct 2020 23:05:49

US3272377

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:05:49

US3272377

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:05:49

US3272377

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:05:49

US3272377

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:05:49

US3272377

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Jan 2016'	System	15 Oct 2020 23:05:49

US3272377

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2016'	System	15 Oct 2020 23:05:49

US3272377

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	15 Oct 2020 23:05:49

US3272377

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	15 Oct 2020 23:05:49

US3272377

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
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)	15 Oct 2020 23:07:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 23:07:30
Data point term sent to Coder	System	15 Oct 2020 23:06:24
User entered 'gastroesophageal reflux disease'	(b) (4), (b) (6)	15 Oct 2020 23:06:13

US3272377

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'UN UNK 1998'	(b) (4), (b) (6)	15 Oct 2020 23:06:13

US3272377

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:06:13

US3272377

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:06:13

US3272377

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:06:13

US3272377

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:06:13

US3272377

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Jan 1998'	System	15 Oct 2020 23:06:13

US3272377

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '1998'	System	15 Oct 2020 23:06:13

US3272377

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	15 Oct 2020 23:06:13

US3272377

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	15 Oct 2020 23:06:13

US3272377

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
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)	15 Oct 2020 23:08:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 23:08:32
Data point term sent to Coder	System	15 Oct 2020 23:07:25
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	15 Oct 2020 23:06:38

US3272377

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'UN UNK 2016'	(b) (4), (b) (6)	15 Oct 2020 23:06:38

US3272377

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:06:38

US3272377

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:06:38

US3272377

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:06:38

US3272377

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:06:38

US3272377

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Jan 2016'	System	15 Oct 2020 23:06:38

US3272377

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2016'	System	15 Oct 2020 23:06:38

US3272377

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	15 Oct 2020 23:06:38

US3272377

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	15 Oct 2020 23:06:38

US3272377

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion cervical spine - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 10:51:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 10:51:38
Data point term sent to Coder	System	15 Oct 2020 23:08:27
User entered 'single level cervical surgical fusion'	(b) (4), (b) (6)	15 Oct 2020 23:07:36

US3272377

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '14 Feb 2018'	(b) (4), (b) (6)	15 Oct 2020 23:07:36

US3272377

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:07:36

US3272377

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:07:36

US3272377

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '14 Feb 2018'	(b) (4), (b) (6)	15 Oct 2020 23:07:36

US3272377

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:07:36

US3272377

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Feb 2018'	System	15 Oct 2020 23:07:36

US3272377

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2018'	System	15 Oct 2020 23:07:36

US3272377

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Feb 2018'	System	15 Oct 2020 23:07:36

US3272377

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2018'	System	15 Oct 2020 23:07:36

US3272377

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion cervical spine - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 10:51:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 10:51:38
Data point term sent to Coder	System	15 Oct 2020 23:09:27
User entered 'single level cervical surgical fusion'	(b) (4), (b) (6)	15 Oct 2020 23:09:01

US3272377

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '14 Feb 2013'	(b) (4), (b) (6)	15 Oct 2020 23:09:01

US3272377

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:09:01

US3272377

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:09:01

US3272377

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '14 Feb 2013'	(b) (4), (b) (6)	15 Oct 2020 23:09:01

US3272377

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:09:01

US3272377

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Feb 2013'	System	15 Oct 2020 23:09:01

US3272377

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2013'	System	15 Oct 2020 23:09:01

US3272377

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Feb 2013'	System	15 Oct 2020 23:09:01

US3272377

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2013'	System	15 Oct 2020 23:09:01

US3272377

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion lumbar spine - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 05:40:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 05:40:28
Data point term sent to Coder	System	15 Oct 2020 23:15:33
User entered 'lumbar single level surgical fusion'	(b) (4), (b) (6)	15 Oct 2020 23:15:06

US3272377

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '27 Nov 2012'	(b) (4), (b) (6)	15 Oct 2020 23:15:06

US3272377

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:15:06

US3272377

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:15:06

US3272377

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '27 Nov 2012'	(b) (4), (b) (6)	15 Oct 2020 23:15:06

US3272377

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:15:06

US3272377

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Nov 2012'	System	15 Oct 2020 23:15:06

US3272377

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2012'	System	15 Oct 2020 23:15:06

US3272377

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Nov 2012'	System	15 Oct 2020 23:15:06

US3272377

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2012'	System	15 Oct 2020 23:15:06

US3272377

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
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: Neck pain, LLT: Cervical pain - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 19:18:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 19:18:00
Data point term sent to Coder	System	25 Feb 2021 19:16:53
Coding entries removed.	Whitney West (b) (4)	25 Feb 2021 19:16:26
User entered 'Chronic CERVICAL PAIN' reason for change: New Information	Whitney West (b) (4)	25 Feb 2021 19:16:26
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: Neck pain, LLT: Cervical pain - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 11:41:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 11:41:50
Data point term sent to Coder	System	20 Nov 2020 16:07:06
User closed query 'DM-Coding: please split the term and report all the events on a separate line with all relevant information, for ex-l, 1) VEHICULAR ACCIDENT 2) HEAD injury,3) CERVICAL pain 3) LUMBAR PAIN.' (Site from System).	System	20 Nov 2020 16:06:55
Query 'DM-Coding: please split the term and report all the events on a separate line with all relevant information, for ex-l, 1) VEHICULAR ACCIDENT 2) HEAD injury,3) CERVICAL pain 3) LUMBAR PAIN.' answered with 'updated' (Site from System).	Kayla Flege (b) (4)	20 Nov 2020 16:06:55
User entered 'CERVICAL PAIN.' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 16:06:50

US3272377

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
User opened query 'DM-Coding: please split the term and report all the events on a separate line with all relevant information, for ex-l, 1) VEHICULAR ACCIDENT 2) HEAD injury,3) CERVICAL pain 3) LUMBAR PAIN.' (Site from System).	Coder Import (b) (4)	12 Nov 2020 08:45:43
Data point term sent to Coder	System	15 Oct 2020 23:23:38
User entered 'vehicular accident - head on collision resulting in cervical and lumbar pain.'	(b) (4), (b) (6)	15 Oct 2020 23:22:53

US3272377

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '11 Jun 2012'	(b) (4), (b) (6)	15 Oct 2020 23:22:53

US3272377

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:46

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:22:53

US3272377

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	25 Feb 2021 19:16:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	25 Feb 2021 19:16:37
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	25 Feb 2021 19:16:26
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:22:53

US3272377

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty; reason for change New Information	Whitney West (b) (4)	25 Feb 2021 19:16:26
User entered '14 Feb 2013' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 16:06:50
User entered '11 Jun 2012'	(b) (4), (b) (6)	15 Oct 2020 23:22:53

US3272377

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:22:53

US3272377

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Jun 2012'	System	15 Oct 2020 23:22:53

US3272377

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2012'	System	15 Oct 2020 23:22:53

US3272377

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	25 Feb 2021 19:16:26
User entered 'Feb 2013'	System	20 Nov 2020 16:06:50
User entered 'Jun 2012'	System	15 Oct 2020 23:22:53

US3272377

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	25 Feb 2021 19:16:26
User entered '2013'	System	20 Nov 2020 16:06:50
User entered '2012'	System	15 Oct 2020 23:22:53

US3272377

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 23:24:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 23:24:32
Data point term sent to Coder	System	15 Oct 2020 23:23:36
User entered 'severe obesity'	(b) (4), (b) (6)	15 Oct 2020 23:23:16

US3272377

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'UN UNK 2012'	(b) (4), (b) (6)	15 Oct 2020 23:23:16

US3272377

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:46

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:23:16

US3272377

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:23:16

US3272377

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:23:16

US3272377

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:23:16

US3272377

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Jan 2012'	System	15 Oct 2020 23:23:16

US3272377

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2012'	System	15 Oct 2020 23:23:16

US3272377

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	15 Oct 2020 23:23:16

US3272377

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	15 Oct 2020 23:23:16

US3272377

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
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: Back pain, LLT: Lumbar pain - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 16:40:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 16:40:01
Data point term sent to Coder	System	20 Nov 2020 16:08:07
User entered 'Lumbar pain'	Kayla Flege (b) (4)	20 Nov 2020 16:07:32

US3272377

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '11 Jun 2012' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 16:29:42
User entered '11 Jun 2020'	Kayla Flege (b) (4)	20 Nov 2020 16:07:32

US3272377

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Kayla Flege (b) (4)	20 Nov 2020 16:07:32

US3272377

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	25 Feb 2021 19:17:41
User entered 'No (N)'	Kayla Flege (b) (4)	20 Nov 2020 16:07:32

US3272377

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty; reason for change New Information	Whitney West (b) (4)	25 Feb 2021 19:17:41
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	20 Nov 2020 16:29:42
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	20 Nov 2020 16:29:33
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	20 Nov 2020 16:29:33
User entered '14 Feb 2013' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 16:29:33
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	20 Nov 2020 16:07:32
User entered '14 Feb 2020'	Kayla Flege (b) (4)	20 Nov 2020 16:07:32

US3272377

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Kayla Flege (b) (4)	20 Nov 2020 16:07:32

US3272377

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Jun 2012'	System	20 Nov 2020 16:29:42
User entered 'Jun 2020'	System	20 Nov 2020 16:07:32

US3272377

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:46

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2012'	System	20 Nov 2020 16:29:42
User entered '2020'	System	20 Nov 2020 16:07:32

US3272377

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	25 Feb 2021 19:17:41
User entered 'Feb 2013'	System	20 Nov 2020 16:29:33
User entered 'Feb 2020'	System	20 Nov 2020 16:07:32

US3272377

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	25 Feb 2021 19:17:41
User entered '2013'	System	20 Nov 2020 16:29:33
User entered '2020'	System	20 Nov 2020 16:07:32

US3272377

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Psychiatric disorders, HLT: Substance abuse, PT: Substance abuse, LLT: Substance abuse - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 15:31:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 15:31:49
Data point term sent to Coder	System	01 Dec 2020 15:30:47
User entered 'Substance abuse'	Whitney West (b) (4)	01 Dec 2020 15:29:51

US3272377

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 15:29:51

US3272377

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'I'	Whitney West (b) (4)	01 Dec 2020 15:29:51

US3272377

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	Whitney West (b) (4)	01 Dec 2020 15:29:51

US3272377

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 15:29:51

US3272377

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 15:29:51

US3272377

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:29:51

US3272377

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:29:51

US3272377

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:29:51

US3272377

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:29:51

US3272377

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol use disorder, LLT: Alcohol use disorder - version MedDRA\23.0.	Coder Import (b) (4)	10 Dec 2020 22:47:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Dec 2020 22:47:53
Data point term sent to Coder	System	01 Dec 2020 15:37:55
User entered 'Severe Alcohol Use Disorder- Not in remission'	Whitney West (b) (4)	01 Dec 2020 15:37:08

US3272377

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 15:37:08

US3272377

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'I'	Whitney West (b) (4)	01 Dec 2020 15:37:08

US3272377

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	Whitney West (b) (4)	01 Dec 2020 15:37:08

US3272377

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 15:37:08

US3272377

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 15:37:08

US3272377

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:37:08

US3272377

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:37:08

US3272377

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:37:08

US3272377

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:37:08

US3272377

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Major depression, LLT: Depression psychotic - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 17:26:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 17:26:43
Data point term sent to Coder	System	01 Dec 2020 15:37:55
User entered 'Major Depressive Disorder Recurrent, Severe, with Psychotic Features'	Whitney West (b) (4)	01 Dec 2020 15:37:39

US3272377

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 15:37:39

US3272377

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'I'	Whitney West (b) (4)	01 Dec 2020 15:37:39

US3272377

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 15:37:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Dec 2020 15:37:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	01 Dec 2020 15:37:57
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 15:37:39
User entered empty.	Whitney West (b) (4)	01 Dec 2020 15:37:39

US3272377

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 15:37:39

US3272377

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 15:37:39

US3272377

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:37:39

US3272377

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:37:39

US3272377

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:37:39

US3272377

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:37:39

US3272377

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 15:39:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 15:39:48
Data point term sent to Coder	System	01 Dec 2020 15:38:56
User entered 'Chronic Kidney Disease'	Whitney West (b) (4)	01 Dec 2020 15:38:24

US3272377

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '06 Nov 2017'	Whitney West (b) (4)	01 Dec 2020 15:38:24

US3272377

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 15:38:24

US3272377

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	Whitney West (b) (4)	01 Dec 2020 15:38:24

US3272377

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 15:38:24

US3272377

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 15:38:24

US3272377

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Nov 2017'	System	01 Dec 2020 15:38:24

US3272377

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2017'	System	01 Dec 2020 15:38:24

US3272377

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:38:24

US3272377

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:38:24

US3272377

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 15:39:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 15:39:49
Data point term sent to Coder	System	01 Dec 2020 15:38:56
User entered 'Hyperlipidemia'	Whitney West (b) (4)	01 Dec 2020 15:38:43

US3272377

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '06 Nov 2017'	Whitney West (b) (4)	01 Dec 2020 15:38:43

US3272377

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 15:38:43

US3272377

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	Whitney West (b) (4)	01 Dec 2020 15:38:43

US3272377

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 15:38:43

US3272377

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 15:38:43

US3272377

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Nov 2017'	System	01 Dec 2020 15:38:43

US3272377

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2017'	System	01 Dec 2020 15:38:43

US3272377

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:38:43

US3272377

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:38:43

US3272377

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 15:40:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 15:40:58
Data point term sent to Coder	System	01 Dec 2020 15:39:58
User entered 'Hypokalemia'	Whitney West (b) (4)	01 Dec 2020 15:39:02

US3272377

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '06 Nov 2017'	Whitney West (b) (4)	01 Dec 2020 15:39:02

US3272377

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 15:39:02

US3272377

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	Whitney West (b) (4)	01 Dec 2020 15:39:02

US3272377

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 15:39:02

US3272377

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 15:39:02

US3272377

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Nov 2017'	System	01 Dec 2020 15:39:02

US3272377

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2017'	System	01 Dec 2020 15:39:02

US3272377

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:39:02

US3272377

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:39:02

US3272377

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Psychiatric disorders, HLG: Schizophrenia and other psychotic disorders, HLT: Schizoaffective and schizophreniform disorders, PT: Schizoaffective disorder bipolar type, LLT: Schizoaffective disorder bipolar type - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 15:40:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 15:40:58
Data point term sent to Coder	System	01 Dec 2020 15:39:56
User entered 'Schizoaffective Disorder Bipolar Type'	Whitney West (b) (4)	01 Dec 2020 15:39:31

US3272377

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '05 Nov 2017'	Whitney West (b) (4)	01 Dec 2020 15:39:31

US3272377

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 15:39:31

US3272377

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	Whitney West (b) (4)	01 Dec 2020 15:39:31

US3272377

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 15:39:31

US3272377

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 15:39:31

US3272377

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'Nov 2017'	System	01 Dec 2020 15:39:31

US3272377

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '2017'	System	01 Dec 2020 15:39:31

US3272377

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:39:31

US3272377

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	01 Dec 2020 15:39:31

US3272377

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Psychiatric disorders, HLG: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicide attempt, LLT: Suicide attempt - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 01:21:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 01:21:05
Data point term sent to Coder	System	14 Dec 2020 23:29:53
User entered 'Suicide attempt, previous'	Whitney West (b) (4)	14 Dec 2020 23:28:55

US3272377

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	14 Dec 2020 23:28:55

US3272377

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:46

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'I'	Whitney West (b) (4)	14 Dec 2020 23:28:55

US3272377

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 23:28:55

US3272377

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	14 Dec 2020 23:28:55

US3272377

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	14 Dec 2020 23:28:55

US3272377

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	14 Dec 2020 23:28:55

US3272377

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	14 Dec 2020 23:28:55

US3272377

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	14 Dec 2020 23:28:55

US3272377

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	14 Dec 2020 23:28:55

US3272377

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug use disorder, LLT: Drug use disorder - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 14:38:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 14:38:52
Data point term sent to Coder	System	14 Dec 2020 23:32:55
User entered 'Severe Stimulant Use Disorder'	Whitney West (b) (4)	14 Dec 2020 23:32:26

US3272377

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	14 Dec 2020 23:32:26

US3272377

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'I'	Whitney West (b) (4)	14 Dec 2020 23:32:26

US3272377

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 23:32:26

US3272377

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	14 Dec 2020 23:32:26

US3272377

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	14 Dec 2020 23:32:26

US3272377

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:46

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	14 Dec 2020 23:32:26

US3272377

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	14 Dec 2020 23:32:26

US3272377

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	14 Dec 2020 23:32:26

US3272377

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered empty.	System	14 Dec 2020 23:32:26

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '11:57'	(b) (4), (b) (6)	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '15 Oct 2020 11:57'	System	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '179.5' cm	(b) (4), (b) (6)	15 Oct 2020 23:24:41
DataPoint set to visible.	System	15 Oct 2020 18:58:46

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '130.8' kg	(b) (4), (b) (6)	15 Oct 2020 23:24:41
DataPoint set to visible.	System	15 Oct 2020 18:58:46

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '40.59559'	System	15 Oct 2020 23:24:41
DataPoint set to visible.	System	15 Oct 2020 18:58:46

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'kg/m2'	System	15 Oct 2020 23:24:41
DataPoint set to visible.	System	15 Oct 2020 18:58:46

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'bpm'	System	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'breaths/min'	System	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'mmHg'	System	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered 'mmHg'	System	15 Oct 2020 23:24:41

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:24:58

US3272377

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:24:58

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'takes kids to park, kids go to school, goes grocery shopping'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:24:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:26:10

US3272377

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 18:55:59

US3272377

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 18:55:59

US3272377

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Oct 2020 18:55:59

US3272377

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'VISIT1'	System	15 Oct 2020 18:55:59

US3272377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 17:48:41

US3272377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:46

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '146664'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 17:48:41

US3272377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	15 Oct 2020 23:26:35
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered by data change (Site from System).	System	15 Oct 2020 23:26:35
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	15 Oct 2020 18:58:33
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 17:48:41

US3272377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:46

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)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 18:56:11

US3272377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:46

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)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 18:56:11

US3272377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 23:26:35
User entered 'No (N)'		15 Oct 2020 18:56:11

US3272377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:46

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 23:26:35
User entered 'No (N)'		15 Oct 2020 18:56:11

US3272377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 18:56:11

US3272377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:24:46

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 18:57:52
DataPoint set to visible.	System	15 Oct 2020 18:57:22

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User accepted default value 'Pre-Dose (PREDOSE)'		15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '11:57'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered '15 Oct 2020 11:57'	System	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '36.8' C	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '77'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'bpm'	System	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '18'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'breaths/min'	System	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	15 Oct 2020 23:28:43
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	15 Oct 2020 23:28:43
User entered '136' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 23:28:43
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	15 Oct 2020 23:28:16
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'mmHg'	System	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 23:28:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		15 Oct 2020 23:28:43
User entered '88' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 23:28:43
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 23:28:16
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'mmHg'	System	15 Oct 2020 23:28:43
User entered empty.	System	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:24:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User accepted default value 'Post-Dose (POSTDOSE)'		15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '13:46'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered '15 Oct 2020 13:46'	System	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '36.8' C	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '79'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'bpm'	System	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '16'	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'breaths/min'	System	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 23:29:02
Query 'Data is required. Please provide.' answered by System data change (Site from System).		15 Oct 2020 23:29:02
User entered '118' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 23:29:02
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 23:28:16
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'mmHg'	System	15 Oct 2020 23:29:02
User entered empty.	System	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 23:29:02
Query 'Data is required. Please provide.' answered by System data change (Site from System).		15 Oct 2020 23:29:02
User entered '88' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 23:29:02
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 23:28:16
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'mmHg'	System	15 Oct 2020 23:29:02
User entered empty.	System	15 Oct 2020 23:28:16

US3272377

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:29:11

US3272377

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 23:29:11

US3272377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 18:59:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 18:59:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 18:59:50
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 18:59:44
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 18:59:44

US3272377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 18:59:44

US3272377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

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)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 18:59:44

US3272377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 18:59:50
User entered empty.	System	15 Oct 2020 18:59:44

US3272377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 18:59:44

US3272377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '13:13'	(b) (4), (b) (6)	15 Oct 2020 18:59:44

US3272377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered '15 Oct 2020 13:13'	System	15 Oct 2020 18:59:44

US3272377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	15 Oct 2020 18:59:44

US3272377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'ONCE'	System	15 Oct 2020 18:59:50
User entered empty.	System	15 Oct 2020 18:59:44

US3272377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 18:59:50
User entered empty.	System	15 Oct 2020 18:59:44

US3272377

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:29:39

US3272377

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 23:29:39

US3272377

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '12:30'	(b) (4), (b) (6)	15 Oct 2020 23:29:39

US3272377

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered '15 Oct 2020 12:30'	System	15 Oct 2020 23:29:39

US3272377

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:24:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 23:29:58

US3272377

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User accepted default value 'Nasopharyngeal Swab (NASAL1)'		15 Oct 2020 23:29:58

US3272377

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:29:58

US3272377

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '12:25'	(b) (4), (b) (6)	15 Oct 2020 23:29:58

US3272377

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:46

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered '15 Oct 2020 12:25'	System	15 Oct 2020 23:29:58

US3272377

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		15 Oct 2020 23:29:58

US3272377

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:29:58

US3272377

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:29:58

US3272377

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered empty.	System	15 Oct 2020 23:29:58

US3272377

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:30:06

US3272377

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:10
User entered 'I'	System	15 Oct 2020 23:30:06

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:00:30', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'f25d80d7-5c51-48d4-9c37-04fc52d46789' User entered 'Yes (Y)'	System	15 Oct 2020 19:01:10
	System	15 Oct 2020 19:01:10

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:00:54', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'f25d80d7-5c51-48d4-9c37-04fc52d46789' User entered '98.3'	System	15 Oct 2020 19:01:10
	System	15 Oct 2020 19:01:10

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:02', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'f25d80d7-5c51-48d4-9c37-04fc52d46789' User entered 'No (N)'	System	15 Oct 2020 19:01:10
	System	15 Oct 2020 19:01:10

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:07', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'f25d80d7-5c51-48d4-9c37-04fc52d46789' User entered '15 Oct 2020 14:01'	System	15 Oct 2020 19:01:10
	System	15 Oct 2020 19:01:10

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '15 Oct 2020 13:33'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '15 Oct 2020 16:03'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:08:15', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '81bb3169-c84e-457e-a4d5-6755578d7e05'	System	15 Oct 2020 22:08:49
User entered 'Yes (Y)'	System	15 Oct 2020 22:08:49

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:08:29', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '81bb3169-c84e-457e-a4d5-6755578d7e05' User entered '98.1'	System	15 Oct 2020 22:08:49
	System	15 Oct 2020 22:08:49

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:08:36', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '81bb3169-c84e-457e-a4d5-6755578d7e05'	System	15 Oct 2020 22:08:49
User entered 'No (N)'	System	15 Oct 2020 22:08:49

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:08:47', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '81bb3169-c84e-457e-a4d5-6755578d7e05' User entered '15 Oct 2020 17:08'	System	15 Oct 2020 22:08:49
	System	15 Oct 2020 22:08:49

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '15 Oct 2020 16:58'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 2'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:37:24', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'd81267b5-8f8e-4913-9b9c-426d06affc4c' User entered 'Yes (Y)'	System	16 Oct 2020 17:37:48
	System	16 Oct 2020 17:37:48

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:37:36', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'd81267b5-8f8e-4913-9b9c-426d06affc4c' User entered '97.3'	System	16 Oct 2020 17:37:48
	System	16 Oct 2020 17:37:48

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:37:41', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'd81267b5-8f8e-4913-9b9c-426d06affc4c' User entered 'No (N)'	System	16 Oct 2020 17:37:48
	System	16 Oct 2020 17:37:48

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:37:44', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'd81267b5-8f8e-4913-9b9c-426d06affc4c' User entered '16 Oct 2020 12:37'	System	16 Oct 2020 17:37:48
	System	16 Oct 2020 17:37:48

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 3'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:38:46', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8081a90a-60e5-4489-9976-a6dd82233373' User entered 'Yes (Y)'	System	17 Oct 2020 19:39:10
	System	17 Oct 2020 19:39:10

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:38:59', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8081a90a-60e5-4489-9976-a6dd82233373' User entered '97.6'	System	17 Oct 2020 19:39:10
	System	17 Oct 2020 19:39:10

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:39:05', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8081a90a-60e5-4489-9976-a6dd82233373'	System	17 Oct 2020 19:39:10
User entered 'No (N)'	System	17 Oct 2020 19:39:10

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:39:07', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8081a90a-60e5-4489-9976-a6dd82233373' User entered '17 Oct 2020 14:39'	System	17 Oct 2020 19:39:10
	System	17 Oct 2020 19:39:10

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 4'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:00:25', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '87d82415-63b2-4dc3-a5a2-e22a8854bda8' User entered 'Yes (Y)'	System	18 Oct 2020 17:00:51
	System	18 Oct 2020 17:00:51

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:00:35', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '87d82415-63b2-4dc3-a5a2-e22a8854bda8' User entered '98.2'	System	18 Oct 2020 17:00:51
	System	18 Oct 2020 17:00:51

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:00:39', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '87d82415-63b2-4dc3-a5a2-e22a8854bda8'	System	18 Oct 2020 17:00:51
User entered 'No (N)'	System	18 Oct 2020 17:00:51

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:00:43', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '87d82415-63b2-4dc3-a5a2-e22a8854bda8' User entered '18 Oct 2020 12:00'	System	18 Oct 2020 17:00:51
	System	18 Oct 2020 17:00:51

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 5'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:35:50', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c5bcca75-544f-421f-a3b3-16a1970d6487' User entered 'Yes (Y)'	System	20 Oct 2020 14:36:21
	System	20 Oct 2020 14:36:21

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:36:04', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c5bcca75-544f-421f-a3b3-16a1970d6487' User entered '98.5'	System	20 Oct 2020 14:36:21
	System	20 Oct 2020 14:36:21

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:36:11', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c5bcca75-544f-421f-a3b3-16a1970d6487'	System	20 Oct 2020 14:36:21
User entered 'No (N)'	System	20 Oct 2020 14:36:21

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:36:19', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c5bcca75-544f-421f-a3b3-16a1970d6487' User entered '20 Oct 2020 09:36'	System	20 Oct 2020 14:36:21
	System	20 Oct 2020 14:36:21

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 6'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:03:20', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'db567534-e110-4b70-800e-aca6a4fe9e64' User entered 'Yes (Y)'	System	20 Oct 2020 17:03:48
	System	20 Oct 2020 17:03:48

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:03:36', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'db567534-e110-4b70-800e-aca6a4fe9e64' User entered '98.5'	System	20 Oct 2020 17:03:48
	System	20 Oct 2020 17:03:48

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:03:40', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'db567534-e110-4b70-800e-aca6a4fe9e64'	System	20 Oct 2020 17:03:48
User entered 'No (N)'	System	20 Oct 2020 17:03:48

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:03:45', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'db567534-e110-4b70-800e-aca6a4fe9e64' User entered '20 Oct 2020 12:03'	System	20 Oct 2020 17:03:48
	System	20 Oct 2020 17:03:48

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 7'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:01', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8892f4f3-2fa4-4636-bba3-4be98ed76ab3' User entered 'Yes (Y)'	System	21 Oct 2020 18:06:17
	System	21 Oct 2020 18:06:17

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:08', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8892f4f3-2fa4-4636-bba3-4be98ed76ab3' User entered '97.1'	System	21 Oct 2020 18:06:17
	System	21 Oct 2020 18:06:17

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:12', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8892f4f3-2fa4-4636-bba3-4be98ed76ab3' User entered 'No (N)'	System	21 Oct 2020 18:06:17
	System	21 Oct 2020 18:06:17

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:15', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8892f4f3-2fa4-4636-bba3-4be98ed76ab3' User entered '21 Oct 2020 13:06'	System	21 Oct 2020 18:06:17
	System	21 Oct 2020 18:06:17

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:19', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '369307cd-3cf7-4c38-b802-f027491521d7' User entered 'None (1)'	System	15 Oct 2020 19:01:38
	System	15 Oct 2020 19:01:38

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:22', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '369307cd-3cf7-4c38-b802-f027491521d7' User entered 'No (N)'	System	15 Oct 2020 19:01:38
	System	15 Oct 2020 19:01:38

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:25', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '369307cd-3cf7-4c38-b802-f027491521d7' User entered 'No (N)'	System	15 Oct 2020 19:01:38
	System	15 Oct 2020 19:01:38

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:29', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '369307cd-3cf7-4c38-b802-f027491521d7' User entered 'None (1)'	System	15 Oct 2020 19:01:38
	System	15 Oct 2020 19:01:38

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:33', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '369307cd-3cf7-4c38-b802-f027491521d7' User entered '15 Oct 2020 14:01'	System	15 Oct 2020 19:01:38
	System	15 Oct 2020 19:01:38

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '15 Oct 2020 13:33'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '15 Oct 2020 16:03'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:08:53', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ec559b6d-fa8f-49c6-b678-fb6fd62df82d' User entered 'None (1)'	System	15 Oct 2020 22:09:17
	System	15 Oct 2020 22:09:17

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:08:57', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ec559b6d-fa8f-49c6-b678-fb6fd62df82d' User entered 'No (N)'	System	15 Oct 2020 22:09:17
	System	15 Oct 2020 22:09:17

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:09:03', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ec559b6d-fa8f-49c6-b678-fb6fd62df82d' User entered 'No (N)'	System	15 Oct 2020 22:09:17
	System	15 Oct 2020 22:09:17

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:09:12', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ec559b6d-fa8f-49c6-b678-fb6fd62df82d' User entered 'None (1)'	System	15 Oct 2020 22:09:17
	System	15 Oct 2020 22:09:17

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:09:15', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ec559b6d-fa8f-49c6-b678-fb6fd62df82d' User entered '15 Oct 2020 17:09'	System	15 Oct 2020 22:09:17
	System	15 Oct 2020 22:09:17

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '15 Oct 2020 16:58'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 2'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:37:50', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '6b40555f-f52c-40fc-8ede-0b07fae56b5f' User entered 'None (1)'	System	16 Oct 2020 17:38:14
	System	16 Oct 2020 17:38:14

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:37:54', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '6b40555f-f52c-40fc-8ede-0b07fae56b5f' User entered 'No (N)'	System	16 Oct 2020 17:38:14
	System	16 Oct 2020 17:38:14

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:37:57', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '6b40555f-f52c-40fc-8ede-0b07fae56b5f' User entered 'No (N)'	System	16 Oct 2020 17:38:14
	System	16 Oct 2020 17:38:14

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:38:09', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '6b40555f-f52c-40fc-8ede-0b07fae56b5f' User entered 'None (1)'	System	16 Oct 2020 17:38:14
	System	16 Oct 2020 17:38:14

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:38:12', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '6b40555f-f52c-40fc-8ede-0b07fae56b5f' User entered '16 Oct 2020 12:38'	System	16 Oct 2020 17:38:14
	System	16 Oct 2020 17:38:14

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 3'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:39:21', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bb389025-9d56-45b2-b1c3-ea392c75e0d2'	System	17 Oct 2020 19:40:05
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 19:40:05

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:39:26', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bb389025-9d56-45b2-b1c3-ea392c75e0d2'	System	17 Oct 2020 19:40:05
User entered 'No (N)'	System	17 Oct 2020 19:40:05

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:39:34', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bb389025-9d56-45b2-b1c3-ea392c75e0d2' User entered 'Yes (Y)'	System	17 Oct 2020 19:40:05
	System	17 Oct 2020 19:40:05

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:39:49', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bb389025-9d56-45b2-b1c3-ea392c75e0d2'	System	17 Oct 2020 19:40:05
User entered '1'	System	17 Oct 2020 19:40:05

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:39:54', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bb389025-9d56-45b2-b1c3-ea392c75e0d2'	System	17 Oct 2020 19:40:05
User entered 'None (1)'	System	17 Oct 2020 19:40:05

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:39:58', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bb389025-9d56-45b2-b1c3-ea392c75e0d2' User entered '17 Oct 2020 14:39'	System	17 Oct 2020 19:40:05
	System	17 Oct 2020 19:40:05

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 4'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:00:49', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ae665578-b656-41a2-aa45-7214d698072e' User entered 'None (1)'	System	18 Oct 2020 17:01:13
	System	18 Oct 2020 17:01:13

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:00:53', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ae665578-b656-41a2-aa45-7214d698072e' User entered 'No (N)'	System	18 Oct 2020 17:01:13
	System	18 Oct 2020 17:01:13

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:00:56', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ae665578-b656-41a2-aa45-7214d698072e' User entered 'No (N)'	System	18 Oct 2020 17:01:13
	System	18 Oct 2020 17:01:13

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:00:59', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ae665578-b656-41a2-aa45-7214d698072e' User entered 'None (1)'	System	18 Oct 2020 17:01:13
	System	18 Oct 2020 17:01:13

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:01:02', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ae665578-b656-41a2-aa45-7214d698072e' User entered '18 Oct 2020 12:01'	System	18 Oct 2020 17:01:13
	System	18 Oct 2020 17:01:13

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 5'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:36:26', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c57cfb42-9456-4cf1-ae80-3e62f5f7ad49'	System	20 Oct 2020 14:37:10
User entered 'None (1)'	System	20 Oct 2020 14:37:10

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:36:30', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c57cfb42-9456-4cf1-ae80-3e62f5f7ad49'	System	20 Oct 2020 14:37:10
User entered 'No (N)'	System	20 Oct 2020 14:37:10

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:36:35', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c57cfb42-9456-4cf1-ae80-3e62f5f7ad49'	System	20 Oct 2020 14:37:10
User entered 'No (N)'	System	20 Oct 2020 14:37:10

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:36:41', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c57cfb42-9456-4cf1-ae80-3e62f5f7ad49'	System	20 Oct 2020 14:37:10
User entered 'None (1)'	System	20 Oct 2020 14:37:10

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:37:07', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c57cfb42-9456-4cf1-ae80-3e62f5f7ad49' User entered '20 Oct 2020 09:37'	System	20 Oct 2020 14:37:10
	System	20 Oct 2020 14:37:10

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 6'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:03:52', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1d9a02b3-48c0-40cd-a24d-34786e348c97'	System	20 Oct 2020 17:04:13
User entered 'None (1)'	System	20 Oct 2020 17:04:13

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:03:56', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1d9a02b3-48c0-40cd-a24d-34786e348c97' User entered 'No (N)'	System	20 Oct 2020 17:04:13
	System	20 Oct 2020 17:04:13

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:04:01', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1d9a02b3-48c0-40cd-a24d-34786e348c97'	System	20 Oct 2020 17:04:13
User entered 'No (N)'	System	20 Oct 2020 17:04:13

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:04:07', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1d9a02b3-48c0-40cd-a24d-34786e348c97'	System	20 Oct 2020 17:04:13
User entered 'None (1)'	System	20 Oct 2020 17:04:13

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:04:11', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1d9a02b3-48c0-40cd-a24d-34786e348c97' User entered '20 Oct 2020 12:04'	System	20 Oct 2020 17:04:13
	System	20 Oct 2020 17:04:13

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 7'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:21', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cc53bdcB-17fa-4ee6-9328-b84dCC20d202' User entered 'None (1)'	System	21 Oct 2020 18:06:36
	System	21 Oct 2020 18:06:36

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:24', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cc53bdc6-17fa-4ee6-9328-b84dcc20d202'	System	21 Oct 2020 18:06:36
User entered 'No (N)'	System	21 Oct 2020 18:06:36

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:27', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cc53bdcB-17fa-4ee6-9328-b84dCC20d202' User entered 'No (N)'	System	21 Oct 2020 18:06:36
	System	21 Oct 2020 18:06:36

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:30', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cc53bdcB-17fa-4ee6-9328-b84dCC20d202' User entered 'None (1)'	System	21 Oct 2020 18:06:36
	System	21 Oct 2020 18:06:36

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:33', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cc53bdcB-17fa-4ee6-9328-b84dCC20d202' User entered '21 Oct 2020 13:06'	System	21 Oct 2020 18:06:36
	System	21 Oct 2020 18:06:36

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:38', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'e7dde595-41a6-436e-a62b-612b81887b90' User entered 'None (0)'	System	15 Oct 2020 19:02:11
	System	15 Oct 2020 19:02:11

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:41', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'e7dde595-41a6-436e-a62b-612b81887b90' User entered 'None (0)'	System	15 Oct 2020 19:02:11
	System	15 Oct 2020 19:02:11

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:47', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'e7dde595-41a6-436e-a62b-612b81887b90' User entered 'None (0)'	System	15 Oct 2020 19:02:11
	System	15 Oct 2020 19:02:11

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:52', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'e7dde595-41a6-436e-a62b-612b81887b90' User entered 'None (0)'	System	15 Oct 2020 19:02:11
	System	15 Oct 2020 19:02:11

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:56', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'e7dde595-41a6-436e-a62b-612b81887b90' User entered 'None (0)'	System	15 Oct 2020 19:02:11
	System	15 Oct 2020 19:02:11

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:01:58', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'e7dde595-41a6-436e-a62b-612b81887b90' User entered 'None (0)'	System	15 Oct 2020 19:02:11
	System	15 Oct 2020 19:02:11

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:02:02', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'e7dde595-41a6-436e-a62b-612b81887b90'	System	15 Oct 2020 19:02:11
User entered 'No (N)'	System	15 Oct 2020 19:02:11

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T14:02:06', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'e7dde595-41a6-436e-a62b-612b81887b90'	System	15 Oct 2020 19:02:11
User entered '15 Oct 2020 14:02'	System	15 Oct 2020 19:02:11

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '15 Oct 2020 13:33'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '15 Oct 2020 16:03'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:09:20', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'd1af626c-522b-427d-ab9d-2dd5def458a3' User entered 'None (0)'	System	15 Oct 2020 22:09:55
	System	15 Oct 2020 22:09:55

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:09:22', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'd1af626c-522b-427d-ab9d-2dd5def458a3' User entered 'None (0)'	System	15 Oct 2020 22:09:55
	System	15 Oct 2020 22:09:55

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:09:26', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'd1af626c-522b-427d-ab9d-2dd5def458a3' User entered 'None (0)'	System	15 Oct 2020 22:09:55
	System	15 Oct 2020 22:09:55

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:09:30', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'd1af626c-522b-427d-ab9d-2dd5def458a3' User entered 'None (0)'	System	15 Oct 2020 22:09:55
	System	15 Oct 2020 22:09:55

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:09:33', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'd1af626c-522b-427d-ab9d-2dd5def458a3' User entered 'None (0)'	System	15 Oct 2020 22:09:55
	System	15 Oct 2020 22:09:55

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:09:36', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'd1af626c-522b-427d-ab9d-2dd5def458a3' User entered 'None (0)'	System	15 Oct 2020 22:09:55
	System	15 Oct 2020 22:09:55

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:09:50', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'd1af626c-522b-427d-ab9d-2dd5def458a3' User entered 'No (N)'	System	15 Oct 2020 22:09:55
	System	15 Oct 2020 22:09:55

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-15T17:09:54', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'd1af626c-522b-427d-ab9d-2dd5def458a3' User entered '15 Oct 2020 17:09'	System	15 Oct 2020 22:09:55
	System	15 Oct 2020 22:09:55

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '15 Oct 2020 16:58'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 2'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:38:17', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c2447fea-f3f2-4713-8cc2-360200c33385' User entered 'None (0)'	System	16 Oct 2020 17:38:53
	System	16 Oct 2020 17:38:53

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:38:21', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c2447fea-f3f2-4713-8cc2-360200c33385' User entered 'None (0)'	System	16 Oct 2020 17:38:53
	System	16 Oct 2020 17:38:53

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:38:25', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c2447fea-f3f2-4713-8cc2-360200c33385' User entered 'None (0)'	System	16 Oct 2020 17:38:53
	System	16 Oct 2020 17:38:53

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:38:34', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c2447fea-f3f2-4713-8cc2-360200c33385' User entered 'None (0)'	System	16 Oct 2020 17:38:53
	System	16 Oct 2020 17:38:53

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:38:37', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c2447fea-f3f2-4713-8cc2-360200c33385' User entered 'None (0)'	System	16 Oct 2020 17:38:53
	System	16 Oct 2020 17:38:53

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:38:43', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c2447fea-f3f2-4713-8cc2-360200c33385' User entered 'None (0)'	System	16 Oct 2020 17:38:53
	System	16 Oct 2020 17:38:53

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:38:47', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c2447fea-f3f2-4713-8cc2-360200c33385'	System	16 Oct 2020 17:38:53
User entered 'No (N)'	System	16 Oct 2020 17:38:53

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-16T12:38:50', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'c2447fea-f3f2-4713-8cc2-360200c33385' User entered '16 Oct 2020 12:38'	System	16 Oct 2020 17:38:53
	System	16 Oct 2020 17:38:53

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 3'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:40:06', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8067ccfb-6b28-493d-a506-c291e7de2c21' User entered 'None (0)'	System	17 Oct 2020 19:40:38
	System	17 Oct 2020 19:40:38

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:40:09', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8067ccfb-6b28-493d-a506-c291e7de2c21' User entered 'None (0)'	System	17 Oct 2020 19:40:38
	System	17 Oct 2020 19:40:38

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:40:14', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8067ccfb-6b28-493d-a506-c291e7de2c21' User entered 'None (0)'	System	17 Oct 2020 19:40:38
	System	17 Oct 2020 19:40:38

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:40:20', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8067ccfb-6b28-493d-a506-c291e7de2c21' User entered 'None (0)'	System	17 Oct 2020 19:40:38
	System	17 Oct 2020 19:40:38

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:40:23', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8067ccfb-6b28-493d-a506-c291e7de2c21' User entered 'None (0)'	System	17 Oct 2020 19:40:38
	System	17 Oct 2020 19:40:38

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:40:26', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8067ccfb-6b28-493d-a506-c291e7de2c21' User entered 'None (0)'	System	17 Oct 2020 19:40:38
	System	17 Oct 2020 19:40:38

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:40:29', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8067ccfb-6b28-493d-a506-c291e7de2c21' User entered 'No (N)'	System	17 Oct 2020 19:40:38
	System	17 Oct 2020 19:40:38

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-17T14:40:32', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8067ccfb-6b28-493d-a506-c291e7de2c21' User entered '17 Oct 2020 14:40'	System	17 Oct 2020 19:40:38
	System	17 Oct 2020 19:40:38

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 4'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:01:07', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '556a0c77-6752-4173-a07f-03cb7634c4cd' User entered 'None (0)'	System	18 Oct 2020 17:01:35
	System	18 Oct 2020 17:01:35

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:01:09', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '556a0c77-6752-4173-a07f-03cb7634c4cd' User entered 'None (0)'	System	18 Oct 2020 17:01:35
	System	18 Oct 2020 17:01:35

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:01:14', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '556a0c77-6752-4173-a07f-03cb7634c4cd' User entered 'None (0)'	System	18 Oct 2020 17:01:35
	System	18 Oct 2020 17:01:35

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:01:17', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '556a0c77-6752-4173-a07f-03cb7634c4cd' User entered 'None (0)'	System	18 Oct 2020 17:01:35
	System	18 Oct 2020 17:01:35

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:01:20', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '556a0c77-6752-4173-a07f-03cb7634c4cd' User entered 'None (0)'	System	18 Oct 2020 17:01:35
	System	18 Oct 2020 17:01:35

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:01:22', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '556a0c77-6752-4173-a07f-03cb7634c4cd' User entered 'None (0)'	System	18 Oct 2020 17:01:35
	System	18 Oct 2020 17:01:35

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:01:25', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '556a0c77-6752-4173-a07f-03cb7634c4cd' User entered 'No (N)'	System	18 Oct 2020 17:01:35
	System	18 Oct 2020 17:01:35

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-18T12:01:28', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '556a0c77-6752-4173-a07f-03cb7634c4cd' User entered '18 Oct 2020 12:01'	System	18 Oct 2020 17:01:35
	System	18 Oct 2020 17:01:35

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 5'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:37:13', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '796aff88-d18d-41fb-a766-4d1851d26327' User entered 'None (0)'	System	20 Oct 2020 14:37:59
	System	20 Oct 2020 14:37:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:37:20', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '796aff88-d18d-41fb-a766-4d1851d26327' User entered 'None (0)'	System	20 Oct 2020 14:37:59
	System	20 Oct 2020 14:37:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:37:33', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '796aff88-d18d-41fb-a766-4d1851d26327' User entered 'None (0)'	System	20 Oct 2020 14:37:59
	System	20 Oct 2020 14:37:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:37:38', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '796aff88-d18d-41fb-a766-4d1851d26327' User entered 'None (0)'	System	20 Oct 2020 14:37:59
	System	20 Oct 2020 14:37:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:37:43', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '796aff88-d18d-41fb-a766-4d1851d26327' User entered 'None (0)'	System	20 Oct 2020 14:37:59
	System	20 Oct 2020 14:37:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:37:46', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '796aff88-d18d-41fb-a766-4d1851d26327' User entered 'None (0)'	System	20 Oct 2020 14:37:59
	System	20 Oct 2020 14:37:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:37:50', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '796aff88-d18d-41fb-a766-4d1851d26327' User entered 'No (N)'	System	20 Oct 2020 14:37:59
	System	20 Oct 2020 14:37:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T09:37:55', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '796aff88-d18d-41fb-a766-4d1851d26327' User entered '20 Oct 2020 09:37'	System	20 Oct 2020 14:37:59
	System	20 Oct 2020 14:37:59

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 6'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:04:23', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '44d1869d-fd69-47dd-9916-92f4e1010938' User entered 'None (0)'	System	20 Oct 2020 17:05:03
	System	20 Oct 2020 17:05:03

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:04:30', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '44d1869d-fd69-47dd-9916-92f4e1010938' User entered 'None (0)'	System	20 Oct 2020 17:05:03
	System	20 Oct 2020 17:05:03

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:04:35', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '44d1869d-fd69-47dd-9916-92f4e1010938' User entered 'None (0)'	System	20 Oct 2020 17:05:03
	System	20 Oct 2020 17:05:03

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:04:39', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '44d1869d-fd69-47dd-9916-92f4e1010938' User entered 'None (0)'	System	20 Oct 2020 17:05:03
	System	20 Oct 2020 17:05:03

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:04:42', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '44d1869d-fd69-47dd-9916-92f4e1010938' User entered 'None (0)'	System	20 Oct 2020 17:05:03
	System	20 Oct 2020 17:05:03

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:04:45', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '44d1869d-fd69-47dd-9916-92f4e1010938' User entered 'None (0)'	System	20 Oct 2020 17:05:03
	System	20 Oct 2020 17:05:03

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:04:53', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '44d1869d-fd69-47dd-9916-92f4e1010938' User entered 'No (N)'	System	20 Oct 2020 17:05:03
	System	20 Oct 2020 17:05:03

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-20T12:05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '44d1869d-fd69-47dd-9916-92f4e1010938' User entered '20 Oct 2020 12:05'	System	20 Oct 2020 17:05:03
	System	20 Oct 2020 17:05:03

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	15 Oct 2020 18:59:44
User entered 'Day 7'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:38', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'feda3c6d-243a-4148-bf1f-648e802f915f' User entered 'None (0)'	System	21 Oct 2020 18:07:08
	System	21 Oct 2020 18:07:08

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:40', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'feda3c6d-243a-4148-bf1f-648e802f915f' User entered 'None (0)'	System	21 Oct 2020 18:07:08
	System	21 Oct 2020 18:07:08

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:46', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'feda3c6d-243a-4148-bf1f-648e802f915f' User entered 'None (0)'	System	21 Oct 2020 18:07:08
	System	21 Oct 2020 18:07:08

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:50', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'feda3c6d-243a-4148-bf1f-648e802f915f' User entered 'None (0)'	System	21 Oct 2020 18:07:08
	System	21 Oct 2020 18:07:08

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:52', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'feda3c6d-243a-4148-bf1f-648e802f915f' User entered 'None (0)'	System	21 Oct 2020 18:07:08
	System	21 Oct 2020 18:07:08

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:55', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'feda3c6d-243a-4148-bf1f-648e802f915f' User entered 'None (0)'	System	21 Oct 2020 18:07:08
	System	21 Oct 2020 18:07:08

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:06:59', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'feda3c6d-243a-4148-bf1f-648e802f915f' User entered 'No (N)'	System	21 Oct 2020 18:07:08
	System	21 Oct 2020 18:07:08

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-10-21T13:07:04', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'feda3c6d-243a-4148-bf1f-648e802f915f' User entered '21 Oct 2020 13:07'	System	21 Oct 2020 18:07:08
	System	21 Oct 2020 18:07:08

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 18:59:44

US3272377

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 18:59:44

US3272377

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:55:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:34:56

US3272377

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:55:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	04 Dec 2020 04:36:44
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'deviation noted' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 21:10:42
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Nov 2020 21:10:31
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 21:10:31
User entered '23 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 18:34:56

US3272377

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:55:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Oct 2020 18:34:56

US3272377

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:55:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 18:34:56

US3272377

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:55:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:35:01

US3272377

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:55:23
User entered 'I'	System	29 Oct 2020 18:35:01

US3272377

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:35:24

US3272377

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '29 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 18:35:24

US3272377

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Oct 2020 18:35:24

US3272377

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 18:35:24

US3272377

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:35:32

US3272377

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:04:58
User entered 'I'	System	29 Oct 2020 18:35:32

US3272377

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:32:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:12:47

US3272377

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:32:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '05 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 18:12:47

US3272377

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:32:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Nov 2020 18:12:47

US3272377

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:32:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:47

US3272377

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:32:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:12:53

US3272377

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:32:13
User entered 'I'	System	05 Nov 2020 18:12:53

US3272377

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:07:06

US3272377

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 21:07:15
User entered '15 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:07:06

US3272377

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Nov 2020 21:07:06

US3272377

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered 'VISIT2'	System	16 Nov 2020 21:07:06

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '13:19'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered '16 Nov 2020 13:19'	System	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '36.3' C	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '90'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered 'bpm'	System	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '16'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered 'breaths/min'	System	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '136'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered 'mmHg'	System	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '82'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:24:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered 'mmHg'	System	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User accepted default value 'Post-Dose (POSTDOSE)'		16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '14:46'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered '16 Nov 2020 14:46'	System	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '36.5' C	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '81'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered 'bpm'	System	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '18'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered 'breaths/min'	System	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '132'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered 'mmHg'	System	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '79'	(b) (4), (b) (6)	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:24:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered 'mmHg'	System	16 Nov 2020 21:08:40

US3272377

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:08:48

US3272377

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:08:48

US3272377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 20:28:17

US3272377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 20:28:17

US3272377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

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)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 20:28:17

US3272377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered 'MRNA-1273 OR PLACEBO'	System	16 Nov 2020 20:28:17

US3272377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 21:07:15
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	16 Nov 2020 21:07:15
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 21:07:06
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 20:28:17

US3272377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '14:10'	(b) (4), (b) (6)	16 Nov 2020 20:28:17

US3272377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered '16 Nov 2020 14:10'	System	16 Nov 2020 20:28:17

US3272377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	16 Nov 2020 20:28:17

US3272377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered 'ONCE'	System	16 Nov 2020 20:28:17

US3272377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:24:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered 'INTRAMUSCULAR'	System	16 Nov 2020 20:28:17

US3272377

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:09:18

US3272377

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:09:18

US3272377

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '13:34'	(b) (4), (b) (6)	16 Nov 2020 21:09:18

US3272377

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered '16 Nov 2020 13:34'	System	16 Nov 2020 21:09:18

US3272377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:24:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:09:32

US3272377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Nov 2020 21:09:32

US3272377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:09:32

US3272377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '13:29'	(b) (4), (b) (6)	16 Nov 2020 21:09:32

US3272377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:24:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered '16 Nov 2020 13:29'	System	16 Nov 2020 21:09:32

US3272377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		16 Nov 2020 21:09:32

US3272377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 21:09:32

US3272377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:09:32

US3272377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:24:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered empty.	System	16 Nov 2020 21:09:32

US3272377

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:09:37

US3272377

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:42:28
User entered '1'	System	16 Nov 2020 21:09:37

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:45:07', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '431bac79-bc0d-4d78-a08c-866364e51bac' User entered 'Yes (Y)'	System	16 Nov 2020 20:46:35
	System	16 Nov 2020 20:46:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:46:20', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '431bac79-bc0d-4d78-a08c-866364e51bac' User entered '97.8'	System	16 Nov 2020 20:46:35
	System	16 Nov 2020 20:46:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:46:25', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '431bac79-bc0d-4d78-a08c-866364e51bac' User entered 'No (N)'	System	16 Nov 2020 20:46:35
	System	16 Nov 2020 20:46:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:46:30', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '431bac79-bc0d-4d78-a08c-866364e51bac' User entered '16 Nov 2020 14:46'	System	16 Nov 2020 20:46:35
	System	16 Nov 2020 20:46:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Nov 2020 14:30'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Nov 2020 17:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:04:24', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '0c07f0cb-8e31-4e01-b30a-c5bac8925725' User entered 'Yes (Y)'	System	17 Nov 2020 12:14:01
	System	17 Nov 2020 12:14:01

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:04:31', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '0c07f0cb-8e31-4e01-b30a-c5bac8925725' User entered '98.2'	System	17 Nov 2020 12:14:01
	System	17 Nov 2020 12:14:01

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:04:34', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '0c07f0cb-8e31-4e01-b30a-c5bac8925725' User entered 'No (N)'	System	17 Nov 2020 12:14:01
	System	17 Nov 2020 12:14:01

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:04:39', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '0c07f0cb-8e31-4e01-b30a-c5bac8925725' User entered '17 Nov 2020 06:04'	System	17 Nov 2020 12:14:01
	System	17 Nov 2020 12:14:01

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Nov 2020 17:55'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 2'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:57:26', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '550c271f-2c8a-4345-bcfa-a661da88604e' User entered 'Yes (Y)'	System	17 Nov 2020 21:57:54
	System	17 Nov 2020 21:57:54

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:57:35', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '550c271f-2c8a-4345-bcfa-a661da88604e' User entered '101.7'	System	17 Nov 2020 21:57:54
	System	17 Nov 2020 21:57:54

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:57:41', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '550c271f-2c8a-4345-bcfa-a661da88604e' User entered 'No (N)'	System	17 Nov 2020 21:57:54
	System	17 Nov 2020 21:57:54

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:57:49', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '550c271f-2c8a-4345-bcfa-a661da88604e' User entered '17 Nov 2020 15:57'	System	17 Nov 2020 21:57:54
	System	17 Nov 2020 21:57:54

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 3'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:30:55', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7c9be712-3ab8-45a4-a3bb-e3b0165971a2' User entered 'Yes (Y)'	System	19 Nov 2020 01:31:35
	System	19 Nov 2020 01:31:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:31:03', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7c9be712-3ab8-45a4-a3bb-e3b0165971a2' User entered '99.8'	System	19 Nov 2020 01:31:35
	System	19 Nov 2020 01:31:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:31:07', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7c9be712-3ab8-45a4-a3bb-e3b0165971a2' User entered 'Yes (Y)'	System	19 Nov 2020 01:31:35
	System	19 Nov 2020 01:31:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4)	-04 Dec 2020 04:44:23
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Kayla Flege (b) (4)	20 Nov 2020 16:01:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:31:28', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7c9be712-3ab8-45a4-a3bb-e3b0165971a2'	(b) (4)	
User entered '1'	System	19 Nov 2020 01:31:35
	System	19 Nov 2020 01:31:35
	System	19 Nov 2020 01:31:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:31:28', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7c9be712-3ab8-45a4-a3bb-e3b0165971a2' User entered '0'	System	19 Nov 2020 01:31:35
	System	19 Nov 2020 01:31:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:31:32', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7c9be712-3ab8-45a4-a3bb-e3b0165971a2' User entered '18 Nov 2020 19:31'	System	19 Nov 2020 01:31:35
	System	19 Nov 2020 01:31:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 4'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 5'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 6'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:20:50', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'a59a1abf-955b-47b1-9d32-55f91ad991b9' User entered 'Yes (Y)'	System	21 Nov 2020 18:21:11
	System	21 Nov 2020 18:21:11

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:21:01', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'a59a1abf-955b-47b1-9d32-55f91ad991b9' User entered '97.4'	System	21 Nov 2020 18:21:11
	System	21 Nov 2020 18:21:11

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:21:04', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'a59a1abf-955b-47b1-9d32-55f91ad991b9' User entered 'No (N)'	System	21 Nov 2020 18:21:11
	System	21 Nov 2020 18:21:11

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:21:09', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'a59a1abf-955b-47b1-9d32-55f91ad991b9' User entered '21 Nov 2020 12:21'	System	21 Nov 2020 18:21:11
	System	21 Nov 2020 18:21:11

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 7'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:46:39', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '928b7ca0-986b-492b-9144-f09430e8baa8' User entered 'None (1)'	System	16 Nov 2020 20:47:06
	System	16 Nov 2020 20:47:06

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:46:45', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '928b7ca0-986b-492b-9144-f09430e8baa8' User entered 'No (N)'	System	16 Nov 2020 20:47:06
	System	16 Nov 2020 20:47:06

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:46:51', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '928b7ca0-986b-492b-9144-f09430e8baa8' User entered 'No (N)'	System	16 Nov 2020 20:47:06
	System	16 Nov 2020 20:47:06

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:46:57', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '928b7ca0-986b-492b-9144-f09430e8baa8' User entered 'None (1)'	System	16 Nov 2020 20:47:06
	System	16 Nov 2020 20:47:06

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:47:01', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '928b7ca0-986b-492b-9144-f09430e8baa8' User entered '16 Nov 2020 14:47'	System	16 Nov 2020 20:47:06
	System	16 Nov 2020 20:47:06

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Nov 2020 14:30'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Nov 2020 17:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:04:43', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '529b273b-fb56-4c27-a85a-e7e642c5a3e8' User entered 'None (1)'	System	17 Nov 2020 12:14:14
	System	17 Nov 2020 12:14:14

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:04:47', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '529b273b-fb56-4c27-a85a-e7e642c5a3e8' User entered 'No (N)'	System	17 Nov 2020 12:14:14
	System	17 Nov 2020 12:14:14

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:04:50', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '529b273b-fb56-4c27-a85a-e7e642c5a3e8' User entered 'No (N)'	System	17 Nov 2020 12:14:14
	System	17 Nov 2020 12:14:14

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:04:59', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '529b273b-fb56-4c27-a85a-e7e642c5a3e8' User entered 'None (1)'	System	17 Nov 2020 12:14:14
	System	17 Nov 2020 12:14:14

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:05:02', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '529b273b-fb56-4c27-a85a-e7e642c5a3e8' User entered '17 Nov 2020 06:05'	System	17 Nov 2020 12:14:14
	System	17 Nov 2020 12:14:14

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Nov 2020 17:55'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 2'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:57:57', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '087d7076-07a6-4e6c-9c03-e40b42f0001b' User entered 'None (1)'	System	17 Nov 2020 21:58:32
	System	17 Nov 2020 21:58:32

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:58:01', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '087d7076-07a6-4e6c-9c03-e40b42f0001b' User entered 'No (N)'	System	17 Nov 2020 21:58:32
	System	17 Nov 2020 21:58:32

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:58:04', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '087d7076-07a6-4e6c-9c03-e40b42f0001b' User entered 'No (N)'	System	17 Nov 2020 21:58:32
	System	17 Nov 2020 21:58:32

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:58:23', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '087d7076-07a6-4e6c-9c03-e40b42f0001b' User entered 'Does not interfere with activity (2)'	System	17 Nov 2020 21:58:32
	System	17 Nov 2020 21:58:32

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:58:29', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '087d7076-07a6-4e6c-9c03-e40b42f0001b' User entered '17 Nov 2020 15:58'	System	17 Nov 2020 21:58:32
	System	17 Nov 2020 21:58:32

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 3'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:32:35', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'b6ab0a41-3b5e-4f58-891c-c523c60aa5e4'	System	19 Nov 2020 01:32:40
User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 01:32:40

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:31:53', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'b6ab0a41-3b5e-4f58-891c-c523c60aa5e4' User entered 'No (N)'	System	19 Nov 2020 01:32:40
	System	19 Nov 2020 01:32:40

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:32:05', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'b6ab0a41-3b5e-4f58-891c-c523c60aa5e4' User entered 'Yes (Y)'	System	19 Nov 2020 01:32:40
	System	19 Nov 2020 01:32:40

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:32:23', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'b6ab0a41-3b5e-4f58-891c-c523c60aa5e4' User entered '1'	System	19 Nov 2020 01:32:40
	System	19 Nov 2020 01:32:40

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:32:28', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'b6ab0a41-3b5e-4f58-891c-c523c60aa5e4'	System	19 Nov 2020 01:32:40
User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 01:32:40

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:32:37', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'b6ab0a41-3b5e-4f58-891c-c523c60aa5e4' User entered '18 Nov 2020 19:32'	System	19 Nov 2020 01:32:40
	System	19 Nov 2020 01:32:40

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 4'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 5'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 6'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:20:22', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '482f93ff-4da4-45c3-b741-e7d770d15dbe'	System	21 Nov 2020 18:20:44
User entered 'None (1)'	System	21 Nov 2020 18:20:44

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:20:26', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '482f93ff-4da4-45c3-b741-e7d770d15dbe' User entered 'No (N)'	System	21 Nov 2020 18:20:44
	System	21 Nov 2020 18:20:44

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:20:30', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '482f93ff-4da4-45c3-b741-e7d770d15dbe' User entered 'No (N)'	System	21 Nov 2020 18:20:44
	System	21 Nov 2020 18:20:44

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:20:34', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '482f93ff-4da4-45c3-b741-e7d770d15dbe' User entered 'None (1)'	System	21 Nov 2020 18:20:44
	System	21 Nov 2020 18:20:44

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:20:39', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '482f93ff-4da4-45c3-b741-e7d770d15dbe' User entered '21 Nov 2020 12:20'	System	21 Nov 2020 18:20:44
	System	21 Nov 2020 18:20:44

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 7'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:47:07', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bf83410c-f0c1-4e68-9c21-b9e2abfc2a04' User entered 'None (0)'	System	16 Nov 2020 20:48:31
	System	16 Nov 2020 20:48:31

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:47:10', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bf83410c-f0c1-4e68-9c21-b9e2abfc2a04' User entered 'None (0)'	System	16 Nov 2020 20:48:31
	System	16 Nov 2020 20:48:31

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:48:11', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bf83410c-f0c1-4e68-9c21-b9e2abfc2a04' User entered 'None (0)'	System	16 Nov 2020 20:48:31
	System	16 Nov 2020 20:48:31

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:48:14', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bf83410c-f0c1-4e68-9c21-b9e2abfc2a04' User entered 'None (0)'	System	16 Nov 2020 20:48:31
	System	16 Nov 2020 20:48:31

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:48:17', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bf83410c-f0c1-4e68-9c21-b9e2abfc2a04' User entered 'None (0)'	System	16 Nov 2020 20:48:31
	System	16 Nov 2020 20:48:31

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:48:21', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bf83410c-f0c1-4e68-9c21-b9e2abfc2a04' User entered 'None (0)'	System	16 Nov 2020 20:48:31
	System	16 Nov 2020 20:48:31

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:48:24', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bf83410c-f0c1-4e68-9c21-b9e2abfc2a04' User entered 'No (N)'	System	16 Nov 2020 20:48:31
	System	16 Nov 2020 20:48:31

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-16T14:48:28', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'bf83410c-f0c1-4e68-9c21-b9e2abfc2a04' User entered '16 Nov 2020 14:48'	System	16 Nov 2020 20:48:31
	System	16 Nov 2020 20:48:31

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Nov 2020 14:30'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Nov 2020 17:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:05:17', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7ad59d29-f202-4426-9ea5-bd7dada99970'	System	17 Nov 2020 12:14:44
User entered 'No interference with activity (1)'	System	17 Nov 2020 12:14:44

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:05:25', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7ad59d29-f202-4426-9ea5-bd7dada99970' User entered 'None (0)'	System	17 Nov 2020 12:14:44
	System	17 Nov 2020 12:14:44

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:05:30', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7ad59d29-f202-4426-9ea5-bd7dada99970' User entered 'None (0)'	System	17 Nov 2020 12:14:44
	System	17 Nov 2020 12:14:44

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:05:34', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7ad59d29-f202-4426-9ea5-bd7dada99970' User entered 'None (0)'	System	17 Nov 2020 12:14:44
	System	17 Nov 2020 12:14:44

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:05:38', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7ad59d29-f202-4426-9ea5-bd7dada99970' User entered 'None (0)'	System	17 Nov 2020 12:14:44
	System	17 Nov 2020 12:14:44

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:05:44', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7ad59d29-f202-4426-9ea5-bd7dada99970' User entered 'None (0)'	System	17 Nov 2020 12:14:44
	System	17 Nov 2020 12:14:44

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:05:47', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7ad59d29-f202-4426-9ea5-bd7dada99970' User entered 'No (N)'	System	17 Nov 2020 12:14:44
	System	17 Nov 2020 12:14:44

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T06:05:54', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '7ad59d29-f202-4426-9ea5-bd7dada99970' User entered '17 Nov 2020 06:05'	System	17 Nov 2020 12:14:44
	System	17 Nov 2020 12:14:44

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '16 Nov 2020 17:55'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 2'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:58:47', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'df02de45-5a10-4a42-af2d-3b8b74555a7c'	System	17 Nov 2020 22:00:05
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	17 Nov 2020 22:00:05

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:58:57', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'df02de45-5a10-4a42-af2d-3b8b74555a7c' User entered 'Significant; prevents daily activity (3)'	System	17 Nov 2020 22:00:05
	System	17 Nov 2020 22:00:05

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:59:03', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'df02de45-5a10-4a42-af2d-3b8b74555a7c' User entered 'Significant; prevents daily activity (3)'	System	17 Nov 2020 22:00:05
	System	17 Nov 2020 22:00:05

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:59:10', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'df02de45-5a10-4a42-af2d-3b8b74555a7c' User entered 'Significant; prevents daily activity (3)'	System	17 Nov 2020 22:00:05
	System	17 Nov 2020 22:00:05

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:59:19', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'df02de45-5a10-4a42-af2d-3b8b74555a7c'	System	17 Nov 2020 22:00:05
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	17 Nov 2020 22:00:05

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:59:25', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'df02de45-5a10-4a42-af2d-3b8b74555a7c'	System	17 Nov 2020 22:00:05
User entered 'Prevents daily activity and requires medical attention (3)'	System	17 Nov 2020 22:00:05

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T15:59:50', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'df02de45-5a10-4a42-af2d-3b8b74555a7c' User entered 'No (N)'	System	17 Nov 2020 22:00:05
	System	17 Nov 2020 22:00:05

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-17T16:00:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'df02de45-5a10-4a42-af2d-3b8b74555a7c' User entered '17 Nov 2020 16:00'	System	17 Nov 2020 22:00:05
	System	17 Nov 2020 22:00:05

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 3'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:32:44', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cb1216e7-129c-4380-a5b9-9a068b73b741'	System	19 Nov 2020 01:33:33
User entered 'No interference with activity (1)'	System	19 Nov 2020 01:33:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:32:54', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cb1216e7-129c-4380-a5b9-9a068b73b741'	System	19 Nov 2020 01:33:33
User entered 'No interference with activity (1)'	System	19 Nov 2020 01:33:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:33:01', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cb1216e7-129c-4380-a5b9-9a068b73b741' User entered 'Some interference with activity (2)'	System	19 Nov 2020 01:33:33
	System	19 Nov 2020 01:33:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:33:05', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cb1216e7-129c-4380-a5b9-9a068b73b741' User entered 'Some interference with activity (2)'	System	19 Nov 2020 01:33:33
	System	19 Nov 2020 01:33:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:33:18', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cb1216e7-129c-4380-a5b9-9a068b73b741'	System	19 Nov 2020 01:33:33
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	19 Nov 2020 01:33:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:33:23', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cb1216e7-129c-4380-a5b9-9a068b73b741'	System	19 Nov 2020 01:33:33
User entered 'Some interference with activity not requiring medical attention (2)'	System	19 Nov 2020 01:33:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:33:27', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cb1216e7-129c-4380-a5b9-9a068b73b741' User entered 'No (N)'	System	19 Nov 2020 01:33:33
	System	19 Nov 2020 01:33:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-18T19:33:30', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'cb1216e7-129c-4380-a5b9-9a068b73b741' User entered '18 Nov 2020 19:33'	System	19 Nov 2020 01:33:33
	System	19 Nov 2020 01:33:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 4'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 5'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 6'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:21:13', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '51078636-f6b4-4938-ade5-d1e69a2a129c' User entered 'None (0)'	System	21 Nov 2020 18:21:33
	System	21 Nov 2020 18:21:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:21:16', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '51078636-f6b4-4938-ade5-d1e69a2a129c' User entered 'None (0)'	System	21 Nov 2020 18:21:33
	System	21 Nov 2020 18:21:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:21:17', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '51078636-f6b4-4938-ade5-d1e69a2a129c' User entered 'None (0)'	System	21 Nov 2020 18:21:33
	System	21 Nov 2020 18:21:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:21:19', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '51078636-f6b4-4938-ade5-d1e69a2a129c' User entered 'None (0)'	System	21 Nov 2020 18:21:33
	System	21 Nov 2020 18:21:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:21:21', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '51078636-f6b4-4938-ade5-d1e69a2a129c' User entered 'None (0)'	System	21 Nov 2020 18:21:33
	System	21 Nov 2020 18:21:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:21:22', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '51078636-f6b4-4938-ade5-d1e69a2a129c' User entered 'None (0)'	System	21 Nov 2020 18:21:33
	System	21 Nov 2020 18:21:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:21:24', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '51078636-f6b4-4938-ade5-d1e69a2a129c' User entered 'No (N)'	System	21 Nov 2020 18:21:33
	System	21 Nov 2020 18:21:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-11-21T12:21:28', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '51078636-f6b4-4938-ade5-d1e69a2a129c' User entered '21 Nov 2020 12:21'	System	21 Nov 2020 18:21:33
	System	21 Nov 2020 18:21:33

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
Data entry locked.	System	16 Nov 2020 20:28:17
User entered 'Day 7'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

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)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 20:28:17

US3272377

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:24:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:35
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 20:28:17

US3272377

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:27:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Nov 2020 21:32:03

US3272377

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:27:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '25 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 17:12:11
User entered '23 Nov 2020'	Whitney West (b) (4)	23 Nov 2020 21:32:03

US3272377

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:27:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 17:12:11
User entered 'Contact Not Made (CONTACT NOT MADE)'	Whitney West (b) (4)	23 Nov 2020 21:32:03

US3272377

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:27:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 17:12:11
User entered 'Call went straight to disconnected. Voicemail not set up.'	Whitney West (b) (4)	23 Nov 2020 21:32:03

US3272377

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:27:01
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 17:12:27

US3272377

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:27:01
User entered 'I'	System	25 Nov 2020 17:12:27

US3272377

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User closed query 'Per CDM: Previous response is noted. Please remove data from all the fields if confirmed as entered in error.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 17:52:29
Query 'Per CDM: Previous response is noted. Please remove data from all the fields if confirmed as entered in error.' answered with 'data is correct as entered' (Site from DM).	Kayla Flege (b) (4)	14 Dec 2020 19:16:44
User opened query 'Per CDM: Previous response is noted. Please remove data from all the fields if confirmed as entered in error.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 16:02:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	07 Dec 2020 16:01:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 23:45:48
Query 'Data is required. Please complete.' answered with 'Filled out in error.' (Site from System).	Whitney West (b) (4)	25 Nov 2020 18:25:22
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 18:25:11
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	25 Nov 2020 18:25:11
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	25 Nov 2020 18:25:11
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	25 Nov 2020 18:25:04
User entered 'Yes (Y)'	Whitney West (b) (4)	25 Nov 2020 18:24:23

US3272377

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Dec 2020 23:46:32
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	02 Dec 2020 23:46:32
User entered '02 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	02 Dec 2020 23:46:32
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Dec 2020 23:45:48
User entered '02 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	02 Dec 2020 23:45:48
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Nov 2020 18:25:04
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	25 Nov 2020 18:25:04
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	25 Nov 2020 18:25:04
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Nov 2020 18:24:23
User entered '25 Nov 2020'	Whitney West (b) (4)	25 Nov 2020 18:24:23

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3272377

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4), (b) (6)	02 Dec 2020 23:45:48
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	25 Nov 2020 18:25:04
User entered 'Contact Made (CONTACT MADE)'	Whitney West (b) (4)	25 Nov 2020 18:24:23

US3272377

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	Whitney West (b) (4)	25 Nov 2020 18:24:23

US3272377

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 23:46:35

US3272377

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:18
User entered 'I'	System	02 Dec 2020 23:46:35

US3272377

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:08:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 23:07:13

US3272377

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:08:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '10 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 23:07:13

US3272377

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:08:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Dec 2020 23:07:13

US3272377

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:08:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 23:07:13

US3272377

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:08:28
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 23:07:17

US3272377

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:08:28
User entered 'I'	System	10 Dec 2020 23:07:17

US3272377

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Kayla Flege (b) (4)	15 Dec 2020 17:37:29

US3272377

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 Dec 2020'	Kayla Flege (b) (4)	15 Dec 2020 17:37:29

US3272377

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4)	15 Dec 2020 17:37:29

US3272377

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User entered 'VISIT3'	System	15 Dec 2020 17:37:29

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Kayla Flege (b) (4)	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 Dec 2020'	Kayla Flege (b) (4)	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '11:15'	Kayla Flege (b) (4)	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User entered '15 Dec 2020 11:15'	System	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '36.7' C	Kayla Flege (b) (4)	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Oral (Oral)'	Kayla Flege (b) (4)	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	Kayla Flege (b) (4)	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '86'	Kayla Flege (b) (4)	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User entered 'bpm'	System	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '16'	Kayla Flege (b) (4)	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User entered 'breaths/min'	System	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '130'	Kayla Flege (b) (4)	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User entered 'mmHg'	System	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '80'	Kayla Flege (b) (4)	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User entered 'mmHg'	System	15 Dec 2020 17:37:58

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08

US3272377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:24:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08

US3272377

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Kayla Flege (b) (4)	15 Dec 2020 17:38:07

US3272377

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:24:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 Dec 2020'	Kayla Flege (b) (4)	15 Dec 2020 17:38:07

US3272377

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Kayla Flege (b) (4)	15 Dec 2020 17:38:20

US3272377

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 Dec 2020'	Kayla Flege (b) (4)	15 Dec 2020 17:38:20

US3272377

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '11:23'	Kayla Flege (b) (4)	15 Dec 2020 17:38:20

US3272377

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User entered '15 Dec 2020 11:23'	System	15 Dec 2020 17:38:20

US3272377

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Kayla Flege (b) (4)	15 Dec 2020 17:38:24

US3272377

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:18:08
User entered 'I'	System	15 Dec 2020 17:38:24

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[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 (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-12-15T11:23:10', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '0831a5c2-2196-4f4c-8fce-14a8ff01f791' User entered 'No (N)'	System	15 Dec 2020 17:23:25
	System	15 Dec 2020 17:23:25

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Have you been exposed to someone with 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 (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-12-15T11:23:15', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '0831a5c2-2196-4f4c-8fce-14a8ff01f791' User entered 'No (N)'	System	15 Dec 2020 17:23:25

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0D87F0BC-1DA3-4CF3-B109-33D27702A597)', Time: '2020-12-15T11:23:23', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '0831a5c2-2196-4f4c-8fce-14a8ff01f791' User entered '15 Dec 2020 11:23:23'	System	15 Dec 2020 17:23:25
	System	15 Dec 2020 17:23:25

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-02-27T09:33:53-06:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8d95769f-74da-43ac-a656-a555e36662b9' User entered 'No (N)'	System	27 Feb 2021 15:34:13
	System	27 Feb 2021 15:34:13

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Have you been exposed to someone with 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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-02-27T09:33:59-06:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8d95769f-74da-43ac-a656-a555e36662b9' User entered 'No (N)'	System	27 Feb 2021 15:34:13
	System	27 Feb 2021 15:34:13

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-02-27T09:34:08-06:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '8d95769f-74da-43ac-a656-a555e36662b9' User entered '27 Feb 2021 15:34:08'	System	27 Feb 2021 15:34:13
	System	27 Feb 2021 15:34:13

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-08T10:51:32-06:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'e4d23315-66b5-4104-8c9e-ad26dae98bab'	System	08 Mar 2021 16:51:47
User entered 'No (N)'	System	08 Mar 2021 16:51:47

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Have you been exposed to someone with 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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-08T10:51:38-06:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'e4d23315-66b5-4104-8c9e-ad26dae98bab'	System	08 Mar 2021 16:51:47
User entered 'No (N)'	System	08 Mar 2021 16:51:47

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-08T10:51:42-06:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'e4d23315-66b5-4104-8c9e-ad26dae98bab' User entered '08 Mar 2021 10:51:42'	System	08 Mar 2021 16:51:47
	System	08 Mar 2021 16:51:47

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-13T23:01:34-06:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '162eeec7-48e2-468c-89d7-d058149b3c9d' User entered 'No (N)'	System	14 Mar 2021 05:05:01
	System	14 Mar 2021 05:05:01

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Have you been exposed to someone with 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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-13T23:01:39-06:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '162eeec7-48e2-468c-89d7-d058149b3c9d' User entered 'No (N)'	System	14 Mar 2021 05:05:01
	System	14 Mar 2021 05:05:01

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-13T23:01:43-06:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '162eeec7-48e2-468c-89d7-d058149b3c9d' User entered '13 Mar 2021 23:01:43'	System	14 Mar 2021 05:05:01
	System	14 Mar 2021 05:05:01

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-20T00:02:30-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '873557e2-d9d7-4deb-a88f-012cec9df40e'	System	20 Mar 2021 05:03:18
User entered 'No (N)'	System	20 Mar 2021 05:03:18

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Have you been exposed to someone with 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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-20T00:02:35-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '873557e2-d9d7-4deb-a88f-012cec9df40e'	System	20 Mar 2021 05:03:18
User entered 'No (N)'	System	20 Mar 2021 05:03:18

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-20T00:02:38-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '873557e2-d9d7-4deb-a88f-012cec9df40e' User entered '20 Mar 2021 00:02:38'	System	20 Mar 2021 05:03:18
	System	20 Mar 2021 05:03:18

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:51:04-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered 'Yes (Y)'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Have you been exposed to someone with 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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:51:13-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered 'No (N)'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:51:52-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered 'Yes (Y)'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '1'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '1'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '0'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '0'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '0'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '0'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '1'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '1'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '1'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5' User entered '0'	System	27 Mar 2021 07:53:50
	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '0'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '0'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '0'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '0'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '0'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '0'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:52:42-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered '0'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Please 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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:53:17-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:53:27-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5'	System	27 Mar 2021 07:53:50
User entered 'No (N)'	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-03-27T02:53:37-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1a75d40b-2291-4f63-a2f7-1ff03cb6c5d5' User entered '27 Mar 2021 02:53:37'	System	27 Mar 2021 07:53:50
	System	27 Mar 2021 07:53:50

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-04-03T09:43:58-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1f79368f-5fbe-4ace-81dc-0392ec8b6ba6'	System	03 Apr 2021 14:44:12
User entered 'No (N)'	System	03 Apr 2021 14:44:12

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Have you been exposed to someone with 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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-04-03T09:44:04-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1f79368f-5fbe-4ace-81dc-0392ec8b6ba6'	System	03 Apr 2021 14:44:12
User entered 'No (N)'	System	03 Apr 2021 14:44:12

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-04-03T09:44:09-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1f79368f-5fbe-4ace-81dc-0392ec8b6ba6'	System	03 Apr 2021 14:44:12
User entered '03 Apr 2021 09:44:09'	System	03 Apr 2021 14:44:12

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-04-10T07:23:05-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '3585cb77-74c0-43e0-9a0e-44b69ebac0d4' User entered 'No (N)'	System	10 Apr 2021 12:23:18
	System	10 Apr 2021 12:23:18

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Have you been exposed to someone with 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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-04-10T07:23:11-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '3585cb77-74c0-43e0-9a0e-44b69ebac0d4'	System	10 Apr 2021 12:23:18
User entered 'No (N)'	System	10 Apr 2021 12:23:18

US3272377

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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-04-10T07:23:15-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '3585cb77-74c0-43e0-9a0e-44b69ebac0d4' User entered '10 Apr 2021 07:23:15'	System	10 Apr 2021 12:23:18
	System	10 Apr 2021 12:23:18

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-04-17T01:41:31-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1d5a2b21-b7c0-441c-9cc5-cdb5192407b7'	System	17 Apr 2021 06:41:49
User entered 'No (N)'	System	17 Apr 2021 06:41:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Have you been exposed to someone with 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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-04-17T01:41:40-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1d5a2b21-b7c0-441c-9cc5-cdb5192407b7'	System	17 Apr 2021 06:41:49
User entered 'No (N)'	System	17 Apr 2021 06:41:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-04-17T01:41:45-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '1d5a2b21-b7c0-441c-9cc5-cdb5192407b7'	System	17 Apr 2021 06:41:49
User entered '17 Apr 2021 01:41:45'	System	17 Apr 2021 06:41:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-04-24T21:31:21-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ceb0284c-c02e-4c2d-9165-285915243721' User entered 'No (N)'	System	25 Apr 2021 02:31:35
	System	25 Apr 2021 02:31:35

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Have you been exposed to someone with 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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-04-24T21:31:26-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ceb0284c-c02e-4c2d-9165-285915243721' User entered 'No (N)'	System	25 Apr 2021 02:31:35
	System	25 Apr 2021 02:31:35

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-04-24T21:31:30-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'ceb0284c-c02e-4c2d-9165-285915243721' User entered '24 Apr 2021 21:31:30'	System	25 Apr 2021 02:31:35
	System	25 Apr 2021 02:31:35

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-05-01T00:17:51-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'afaca727-b044-4e27-99a7-904dd1a167a1'	System	01 May 2021 05:27:37
User entered 'No (N)'	System	01 May 2021 05:27:37

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

Have you been exposed to someone with 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 (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-05-01T00:17:56-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'afaca727-b044-4e27-99a7-904dd1a167a1'	System	01 May 2021 05:27:37
User entered 'No (N)'	System	01 May 2021 05:27:37

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-05-01T00:18:02-05:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: 'afaca727-b044-4e27-99a7-904dd1a167a1'	System	01 May 2021 05:27:37
User entered '01 May 2021 00:18:02'	System	01 May 2021 05:27:37

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:46:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:46:49

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '10 Dec 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '14 Dec 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '17 Dec 2022 00:01'	System	20 Nov 2020 12:46:49

US3272377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:24:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:46:49
Amendment Manager: User entered '21 Dec 2022 23:59'	System	20 Nov 2020 12:46:49

US3272377

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:24:46

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)	30 Apr 2021 15:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-02-27T09:34:20-06:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '2c87e53d-9e60-422b-bf56-42b6619379f5'	System	27 Feb 2021 15:34:27
User entered 'No (N)'	System	27 Feb 2021 15:34:27

US3272377

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:24:46

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4DCE308F-1B94-41B7-8351-AD38915E03E5)', Time: '2021-02-27T09:34:24-06:00', User OID: 'PatientReportedOutcome (US3272377)', ODM File OID: '2c87e53d-9e60-422b-bf56-42b6619379f5' User entered '27 Feb 2021 15:34:24'	System	27 Feb 2021 15:34:27
	System	27 Feb 2021 15:34:27

US3272377

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:37:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Whitney West (b) (4)	13 Jan 2021 00:26:33

US3272377

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:37:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '12 Jan 2021'	Whitney West (b) (4)	13 Jan 2021 00:26:33

US3272377

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:37:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Contact Made (CONTACT MADE)'	Whitney West (b) (4)	13 Jan 2021 00:26:33

US3272377

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:37:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	Whitney West (b) (4)	13 Jan 2021 00:26:33

US3272377

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:37:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Whitney West (b) (4)	13 Jan 2021 00:26:19

US3272377

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:37:25
User entered 'I'	System	13 Jan 2021 00:26:19

US3272377

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 18:16:23

US3272377

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '11 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 18:16:23

US3272377

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Feb 2021 18:16:23

US3272377

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 18:16:23

US3272377

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 18:13:33

US3272377

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:52:59
User entered 'I'	System	19 Feb 2021 18:13:33

US3272377

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Ashley Bell (b) (4)	30 Mar 2021 00:49:47

US3272377

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '15 Mar 2021'	Ashley Bell (b) (4)	30 Mar 2021 00:49:47

US3272377

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Contact Made (CONTACT MADE)'	Ashley Bell (b) (4)	30 Mar 2021 00:49:47

US3272377

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 00:49:47

US3272377

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 18:13:40

US3272377

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:24:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:29:22
User entered 'I'	System	19 Feb 2021 18:13:40

US3272377

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User closed query 'Per CDM: Please update when visit is conducted. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 13:55:32
Query 'Per CDM: Please update when visit is conducted. Thank you.' answered by data change (Site from DM).	System	22 Apr 2021 15:55:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 15:55:26
User opened query 'Per CDM: Please update when visit is conducted. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 09:57:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 12:43:33
Query 'Data is required. Please complete.' answered with 'Wrong day. Not due yet. ' (Site from System).	Whitney West (b) (4)	25 Feb 2021 19:11:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 18:16:12
User entered empty; reason for change Data Entry Error	System	19 Feb 2021 18:16:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 18:13:51

US3272377

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '13 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 15:55:26
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Feb 2021 18:16:12
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	19 Feb 2021 18:16:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 18:16:12
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Feb 2021 18:13:51
User entered '11 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 18:13:51

US3272377

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 15:55:26
User entered empty; reason for change Data Entry Error		19 Feb 2021 18:16:12
User entered 'Contact Made (CONTACT MADE)'		19 Feb 2021 18:13:51

US3272377

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:24:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 18:13:51

US3272377

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

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 21:13:27

US3272377

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

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '27 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 21:13:27

US3272377

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

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Clinic (Clinic)'	Andrea Clement (b) (4)	01 Mar 2021 21:13:27

US3272377

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

Form: Visit Date

Generated On: 09 Jun 2021 16:24:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User entered 'UNBLND_DECIDE'	System	01 Mar 2021 21:13:27

US3272377

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:46

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '27 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 21:14:38

US3272377

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:46

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 13:58:39
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:34:53

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:46

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 21:14:38

US3272377

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:46

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User closed query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 14:57:23
Query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 13:59:54
User entered 'Amendment 6 or later (Amendment 6 or later)'		22 Apr 2021 13:58:39
User opened query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).		22 Apr 2021 04:45:52
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:34:53

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:46

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '27 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 21:14:38

US3272377

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'mRNA-1273 (mRNA-1273)'	Andrea Clement (b) (4)	01 Mar 2021 21:14:38

US3272377

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:46

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'mRNA-1273 (mRNA-1273)'	Andrea Clement (b) (4)	01 Mar 2021 21:14:38

US3272377

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:46

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'mRNA-1273 (mRNA-1273)'	Andrea Clement (b) (4)	01 Mar 2021 21:14:38

US3272377

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:46

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'No (N)'	Andrea Clement (b) (4)	01 Mar 2021 21:14:38

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:46

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User entered empty.	System	01 Mar 2021 21:14:38

US3272377

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

Form: Unblinding

Generated On: 09 Jun 2021 16:24:46

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User entered empty.	System	01 Mar 2021 21:14:38

US3272377

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 21:14:57

US3272377

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '27 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 21:14:57

US3272377

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '09:27'	Andrea Clement (b) (4)	01 Mar 2021 21:14:57

US3272377

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:24:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User entered '27 Feb 2021 09:27'	System	01 Mar 2021 21:14:57

US3272377

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:24:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'Yes (Y)'	Andrea Clement (b) (4)	01 Mar 2021 21:15:19

US3272377

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:24:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '27 Feb 2021'	Andrea Clement (b) (4)	01 Mar 2021 21:15:19

US3272377

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:24:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '09:26'	Andrea Clement (b) (4)	01 Mar 2021 21:15:19

US3272377

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:24:46

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:33:26
User entered '27 Feb 2021 09:26'	System	01 Mar 2021 21:15:19

US3272377

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:24:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:13:32
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:09
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	25 Nov 2020 17:18:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 21:17:05
User entered 'Yes (Y)'		16 Nov 2020 21:16:58

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	6 Jan 2021 15:23:40
Reviewed for Safety.		5 Dec 2020 13:59:20
User entered 'USA-US070-2020-mRNA-1273-P301000026'		1 Dec 2020 14:33:49

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User coded data point as SOC: Psychiatric disorders, HLG: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicidal ideation, LLT: Suicidal ideation - version MedDRA\23.0.	Coder Import (b) (4)	01 Dec 2020 00:31:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Dec 2020 00:31:05
Data point term sent to Coder	System	01 Dec 2020 00:30:24
User entered 'Suicidal Ideation'	Andrea Clement (b) (4)	01 Dec 2020 00:29:32
	(b) (4)	

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered '21 Nov 2020'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered empty.	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered '30 Nov 2020'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered empty.	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered 'Grade 4 (Grade 4)'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered '0'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered '0'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered 'I'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered '21 Nov 2020'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered '30 Nov 2020'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered empty.	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered '0'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered '0'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered '0'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User closed query 'PV Query: As the last dose of study drug was given on date 16 Nov 2020, please update the action taken with study drug for event of suicidal ideation from none to not applicable.' (Site from Safety).	(b) (4)	15 Dec 2020 13:59:11
Query 'PV Query: As the last dose of study drug was given on date 16 Nov 2020, please update the action taken with study drug for event of suicidal ideation from none to not applicable.' answered with 'Not applicable. The last dose had already been given. ' (Site from Safety).	Whitney West (b) (4)	14 Dec 2020 23:26:33
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Whitney West (b) (4)	14 Dec 2020 23:26:04
User opened query 'PV Query: As the last dose of study drug was given on date 16 Nov 2020, please update the action taken with study drug for event of suicidal ideation from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 20:25:17
User entered 'None (NONE)'	Andrea Clement (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered '0'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication indication recorded that matches this AE term. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 11:49:13
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication indication recorded that matches this AE term. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Updated medications to match updated AEs. ' (Site from DM).	Whitney West (b) (4) (b) (4)	19 Feb 2021 22:26:02
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication indication recorded that matches this AE term. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 19:18:55
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered 'I'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered '0'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User closed query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 13:59:14
Query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' answered with 'Participant still has psychiatric conditions, but is not acutely suicidal and has contracted for safety. He still has severe major depression. ' (Site from Safety).	Whitney West (b) (4)	14 Dec 2020 23:25:34
User opened query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 20:26:12
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Andrea Clement (b) (4)	01 Dec 2020 00:29:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User entered 'Pt has history of Major Depressive disorder, recurrent, severe, with psychotic features. The suicidal ideation is resolved, but not the mental illness associated.'	Andrea Clement (b) (4) (b) (4)	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:23:40
User closed query 'PV Query: Please clarify whether the event of suicidal ideation was caused by major depressive disorder recurrence, severe with psychotic features, since the subject used crack cocaine hours before admission, had a history of alcohol abuse, and had a history of schizoaffective disorder bipolar type. ' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:30:30
Query 'PV Query: Please clarify whether the event of suicidal ideation was caused by major depressive disorder recurrence, severe with psychotic features, since the subject used crack cocaine hours before admission, had a history of alcohol abuse, and had a history of schizoaffective disorder bipolar type. ' answered with 'Subject's suicidal ideation is secondary to subject's MAJOR DEPRESSIVE DISORDER, RECURRENT, SEVERE WITH PSYCHOTIC FEATURES. Exacerbation of chronic, severe underlying condition, worsened by recent substance abuse. Can change adverse event name to reflect updated information. ' (Site from Safety).	Whitney West (b) (4)	26 Dec 2020 22:47:09
User opened query 'PV Query: Please clarify whether the event of suicidal ideation was caused by major depressive disorder recurrence, severe with psychotic features, since the subject used crack cocaine hours before admission, had a history of alcohol abuse, and had a history of schizoaffective disorder bipolar type. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 20:07:24
User closed query 'PV Query: If the subject had a pervious history of suicidal ideation or substance abuse, please consider adding it to medical history.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 13:59:15
Query 'PV Query: If the subject had a pervious history of suicidal ideation or substance abuse, please consider adding it to medical history.' answered with 'Will add. ' (Site from Safety).	Whitney West (b) (4)	14 Dec 2020 23:26:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT WENT TO THE ER ON 21NOV2020 DUE TO SUICIDAL IDEATION. HE WAS ADMITTED TO ACH IMMANUEL MEDICAL CLINIC FOR INPATIENT TREATMENT ON 22NOV2020 DUE TO SUICIDAL IDEATION AND MULTIPLE PSYCHIATRIC DISORDERS AND SUBSTANCE ABUSE THAT HE HAS A HISTORY OF. LAB INCLUDING CBC, CMP, DRUG SCREEN AND ALCOHOL LEVELS WERE PERFORMED ON 21NOV2020 AT THE ER DEPARTMENT (ST. FRANCIS IN GI) BEFORE TRANSFERRING TO OMAHA. DRUG SCREEN WAS POSITIVE FOR OPIATES, AND COCAINE. COVID 19 TEST PERFORMED AND WAS NEG ON 22NOV2020. SEE MEDICAL RECORDS. See medical history.'	Whitney West (b) (4)	14 Dec 2020 23:26:04
reason for change: Data Entry Error		
User opened query 'PV Query: If the subject had a pervious history of suicidal ideation or substance abuse, please consider adding it to medical history.'	(b) (4), (b) (6)	04 Dec 2020 20:25:58
(Site from Safety).		
User entered 'Pt went to the ER on 21NOV2020 due to suicidal ideation. He was admitted to ACH Immanuel Medical Clinic for inpatient treatment on 22NOV2020 due to suicidal ideation and multiple psychiatric disorders and substance abuse that he has a history of. Lab including CBC, CMP, Drug screen and alcohol levels were performed on 21NOV2020 at the ER department (St. Francis in GI) before transferring to Omaha. Drug screen was positive for opiates, and Cocaine. CoVid 19 test performed and was Neg on 22NOV2020. See medical records.'	Andrea Clement (b) (4)	01 Dec 2020 00:29:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 00:29:32

US3272377

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
User entered '0'	System	01 Dec 2020 00:29:32

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:13:32
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:16:52
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:16:45
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'subject stated normal medications taken no new meds need to be listed' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 22:24:53
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Subject stated took normal medication no new con meds needed' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 22:22:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:39:58
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.'	(b) (4), (b) (6)	03 Feb 2021 09:28:10
' (Site from DM). User entered 'Yes (Y)'		15 Oct 2020 23:30:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
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)	15 Oct 2020 23:32:35
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 23:32:35
Data point term sent to Coder	System	15 Oct 2020 23:31:42
User entered 'omeprazole'	(b) (4), (b) (6)	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'gastroesophageal reflux disease'	(b) (4), (b) (6)	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '20'	(b) (4), (b) (6)	15 Oct 2020 23:31:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:31:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:31:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'UN UNK 2016'	(b) (4), (b) (6)	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:31:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 23:31:23

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 23:33:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 23:33:35
Data point term sent to Coder	System	15 Oct 2020 23:32:42
User entered 'amlodipine'	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'hypertension'	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '10'	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'UN UNK 2016'	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 23:32:17

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
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)	16 Oct 2020 14:42:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 14:42:25
Data point term sent to Coder	System	16 Oct 2020 14:37:25
User entered 'Metformin'	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'diabetes mellitus type 2'	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '1000' reason for change: New Information	Whitney West (b) (4)	01 Dec 2020 00:12:09
User entered '500'	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'twice daily (BID)'	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'UN UNK 2016'	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 14:36:58

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 08:52:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 08:52:18
Data point term sent to Coder	System	16 Oct 2020 14:40:29
User entered 'Spring Valley - Super Vitamin B-Complex'	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'nutritional supplement'	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'UN UNK 2019'	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 14:39:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 16:35:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 16:35:02
Data point term sent to Coder	System	20 Nov 2020 16:02:57
User entered 'Acetaminophen'	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Fever'	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '1000'	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'mg (mg)'	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'as needed (PRN)'	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:02:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 16:02:24
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 16:02:24
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:02:14
User entered empty.	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '18 Oct 2020'	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)'	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Kayla Flege (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Per CDM: Response Noted "Subject self reported fever". However no eDairy recorded for this indication during this time frame and "was this medication taken for solicited event?" noted as YES. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 10:42:00
Query 'Per CDM: Response Noted "Subject self reported fever". However no eDairy recorded for this indication during this time frame and "was this medication taken for solicited event?" noted as YES. Please review and update accordingly. Else clarify.' answered with 'subject self reported fever because the edairy was incorrectly entered.' (Site from DM).		29 Dec 2020 21:12:44
User opened query 'Per CDM: Response Noted "Subject self reported fever". However no eDairy recorded for this indication during this time frame and "was this medication taken for solicited event?" noted as YES. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 07:35:01
User closed query '		28 Dec 2020 07:35:01
Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary. Please note that this CM was given at Day 4 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).		
Query '	Kayla Flege (b) (4) (b) (4)	14 Dec 2020 19:16:22
Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary. Please note that this CM was given at Day 4 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' answered with 'subject self reported fever' (Site from DM).		

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query ' Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary. Please note that this CM was given at Day 4 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:58:53
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 16:02:14

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 06:40:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 06:40:12
Data point term sent to Coder	System	01 Dec 2020 00:01:05
User entered 'Amitriptyline'	Whitney West (b) (4) (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Severe, Major Recurrent Depression'	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '50'	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'mg (mg)'	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'once daily (QD)'	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Oral (ORAL)'	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'I'	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	01 Dec 2020 00:01:07
User entered 'Yes (Y)'	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	01 Dec 2020 00:01:07
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	01 Dec 2020 00:00:33
User entered '22 Nov 2020'	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User entered '1'	System	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User entered '1'	System	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:47
User entered '804 (804)'	System	01 Dec 2020 00:00:33

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 00:34:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 00:34:37
Data point term sent to Coder	System	01 Dec 2020 00:03:12
User entered 'Famotidine'	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Gastroesophageal Reflux Disease'	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '40'	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'mg (mg)'	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'once daily (QD)'	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Oral (ORAL)'	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'I'	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '22 Nov 2020'	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User entered '1'	System	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User entered '1'	System	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:07:51
User entered '804 (804)'	System	01 Dec 2020 00:02:30

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Per DM CLR: Con Med IBUPROFEN was added/changed on 18 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 10:54:52
Query 'Per DM CLR: Con Med IBUPROFEN was added/changed on 18 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of th medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'updated' (Site from DM).		02 Mar 2021 18:10:05
User opened query 'Per DM CLR: Con Med IBUPROFEN was added/changed on 18 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).		02 Mar 2021 17:38:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 08:12:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 08:12:08
Data point term sent to Coder	System	25 Feb 2021 19:15:52
Data point term sent to Coder	System	19 Feb 2021 22:18:40
Coding entries removed.	Whitney West (b) (4) (b) (4)	19 Feb 2021 22:18:06

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Name of Medication](#)

Audit	User		Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	01 Dec 2020 00:08:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	01 Dec 2020 00:08:13
Data point term sent to Coder	System		01 Dec 2020 00:04:13
User entered 'Ibuprofen'	Whitney West (b) (4)	(b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Per CDM: Response noted however, please verify if this pertains to #7 CERVICAL PAIN and # 9 LUMBAR PAIN (start/stop date 11-JUN-2012; 14-FEB-2013) in the Medical History eCRF? If yes, note that Con Med start date is after the MH condition stopped?. Please review date(s) and update accordingly or, add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 13:28:01
User entered 'chronic LUMBAR PAIN, chronic CERVICAL PAIN' reason for change: Per Query Resolution	Whitney West (b) (4)	25 Feb 2021 19:15:47
Query 'Per CDM: Response noted however, please verify if this pertains to #7 CERVICAL PAIN and # 9 LUMBAR PAIN (start/stop date 11-JUN-2012; 14-FEB-2013) in the Medical History eCRF? If yes, note that Con Med start date is after the MH condition stopped?. Please review date(s) and update accordingly or, add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'Participant is an unreliable historian. He did report stop dates for lumbar/cervical pain at the time of screening, however the conditions still existed and was treated with medications per his medical records. I will update his medical history reflect the chronic nature of the conditions. Thank you! ' (Site from DM).	Whitney West (b) (4)	25 Feb 2021 19:15:30
User opened query 'Per CDM: Response noted however, please verify if this pertains to #7 CERVICAL PAIN and # 9 LUMBAR PAIN (start/stop date 11-JUN-2012; 14-FEB-2013) in the Medical History eCRF? If yes, note that Con Med start date is after the MH condition stopped?. Please review date(s) and update accordingly or, add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:22:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:22:12
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Updated to match query.' (Site from DM).	Whitney West (b) (4)	19 Feb 2021 22:18:16
User entered 'Lumbar pain, cervical pain' reason for change: Per Query Resolution	Whitney West (b) (4)	19 Feb 2021 22:18:06
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 04:49:23
User entered 'Chronic neck and back pain'	Whitney West (b) (4)	01 Dec 2020 00:03:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '800'	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'mg (mg)'	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'as needed (PRN)'	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Oral (ORAL)'	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '18 Nov 2017' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 18:09:55
User entered '18 Nov 2020'	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '22 Nov 2020'	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User entered empty.	System	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User entered empty.	System	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:00
User entered empty.	System	01 Dec 2020 00:03:42

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 13:50:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 13:50:44
Data point term sent to Coder	System	19 Feb 2021 22:21:46
Coding entries removed.	Whitney West (b) (4)	19 Feb 2021 22:21:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 06:42:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 06:42:09
Data point term sent to Coder	System	01 Dec 2020 00:05:14
User entered 'Aripiprazole'	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 21:57:15
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Suicidal ideation' reason for change: Per Query Resolution	Whitney West (b) (4)	19 Feb 2021 22:21:41
User entered 'Major Depressive Disorder'	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '5'	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'mg (mg)'	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'once daily (QD)'	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Oral (ORAL)'	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '30 Nov 2020'	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
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)	04 Mar 2021 10:17:34
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 'ongoing as medication taken as prophylaxis to prevent suicidal ideation' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 21:57:07
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).		02 Mar 2021 17:38:07
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Dec 2020 00:04:27

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: NORTRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:33:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:33:42
Data point term sent to Coder	System	19 Feb 2021 22:22:46
Coding entries removed.	Whitney West (b) (4)	19 Feb 2021 22:22:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: NORTRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 09:38:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 09:38:08
Data point term sent to Coder	System	01 Dec 2020 00:08:15
User entered 'Nortriptyline'	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 22:08:21
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Suicidal Ideation' reason for change: Per Query Resolution	Whitney West (b) (4)	19 Feb 2021 22:22:08
User entered 'Major Depressive Disorder'	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '50'	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'mg (mg)'	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'once daily (QD)'	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Oral (ORAL)'	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '30 Nov 2020'	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '0'	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
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)	04 Mar 2021 10:17:55
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 'still ongoing as subject using as prophylaxis to prevent future suicidal ideation' (Site from DM).		03 Mar 2021 22:09:12
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)	02 Mar 2021 17:38:33
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Dec 2020 00:07:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
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/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 19:21:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 19:21:01
Data point term sent to Coder	System	25 Feb 2021 19:19:55
Coding entries removed.	Whitney West (b) (4)	25 Feb 2021 19:19:47
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/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 22:15:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 22:15:57
Data point term sent to Coder	System	19 Feb 2021 22:15:37
Coding entries removed.	Whitney West (b) (4)	19 Feb 2021 22:14:41

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Name of Medication](#)

Audit	User	Time (GMT)
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/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 00:10:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 00:10:06
Data point term sent to Coder	System	01 Dec 2020 00:09:15
User entered 'Hydrocodone/Acetaminophen'	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User closed query 'Per CDM: Response noted however, please verify if this pertains to #7 CERVICAL PAIN and # 9 LUMBAR PAIN (start/stop date 11-JUN-2012; 14-FEB-2013) in the Medical History eCRF? If yes, note that Con Med start date is after the MH condition stopped?. Please review date(s) and update accordingly or, add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 13:28:13
Query 'Per CDM: Response noted however, please verify if this pertains to #7 CERVICAL PAIN and # 9 LUMBAR PAIN (start/stop date 11-JUN-2012; 14-FEB-2013) in the Medical History eCRF? If yes, note that Con Med start date is after the MH condition stopped?. Please review date(s) and update accordingly or, add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'Updated the screening medical history. Participant is an unreliable historian. Per medical records, conditions are chronic in nature.' (Site from DM).	Whitney West (b) (4)	25 Feb 2021 19:20:20
User entered 'Chronic LUMBAR PAIN, Chronic CERVICAL PAIN' reason for change: New Information	Whitney West (b) (4)	25 Feb 2021 19:19:47
User opened query 'Per CDM: Response noted however, please verify if this pertains to #7 CERVICAL PAIN and # 9 LUMBAR PAIN (start/stop date 11-JUN-2012; 14-FEB-2013) in the Medical History eCRF? If yes, note that Con Med start date is after the MH condition stopped?. Please review date(s) and update accordingly or, add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:19:32
User closed query 'Per DM CLR: Please note that there is no MH that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:14:46

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no MH Whitney West (b) (4) that matches this Con Med indication during this time (b) (4) frame. Please review Con Med use and add a medical condition and all applicable details to the MH eCRF as appropriate.' answered with 'Updated to match query. ' (Site from DM).	Whitney West (b) (4)	19 Feb 2021 22:14:51
User entered 'Lumbar pain, cervical pain' reason for change: Per Query Resolution	Whitney West (b) (4)	19 Feb 2021 22:14:41
User opened query 'Per DM CLR: Please note that there is no MH that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 04:49:08
User entered 'Chronic neck and chronic back pain'	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '10/325'	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'mg (mg)'	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'once daily (QD)'	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Oral (ORAL)'	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'I'	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '22 Nov 2020'	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User entered '1'	System	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User entered '1'	System	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:07
User entered '804 (804)'	System	01 Dec 2020 00:08:59

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 09:35:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 09:35:19
Data point term sent to Coder	System	01 Dec 2020 00:10:16
User entered 'Naproxen'	Whitney West (b) (4) (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Chronic neck and chronic back pain'	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '500'	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'mg (mg)'	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'twice daily (BID)'	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Oral (ORAL)'	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'I'	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '30 Nov 2020'	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User entered '2'	System	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User entered '1'	System	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:11
User entered '804 (804)'	System	01 Dec 2020 00:09:53

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 06:48:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 06:48:29
Data point term sent to Coder	System	01 Dec 2020 00:11:16
User entered 'Bupropion 24 hour'	Whitney West (b) (4) (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Major Depressive Disorder'	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '150'	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'mg (mg)'	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'once daily (QD)'	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'Oral (ORAL)'	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered empty.	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'I'	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered '30 Nov 2020'	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User entered '1'	System	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User entered '1'	System	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:24:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:08:16
User entered '804 (804)'	System	01 Dec 2020 00:11:04

US3272377

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:24:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:15:42
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 19:31:18

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'USA-US070-2020-MRNA-1273-P301000026'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Adam'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Brosz'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered '2444 W. Faidley Ave'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Grand Island'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'NE'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered '68803'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		01 Dec 2020 14:34:03
User entered 'US'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Feb 2021 18:01:50
User entered '5'	System	28 Dec 2020 18:31:18
User entered '4'	System	15 Dec 2020 15:55:56
User entered '3'	System	15 Dec 2020 13:59:43
User entered '2'	System	01 Dec 2020 14:34:19
User entered '1'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'USA-US070-2020-MRNA-1273-P301000026'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Adam'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Brosz'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered '2444 W. Faidley Ave'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Grand Island'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'NE'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered '68803'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 14:34:03
User entered 'US'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Feb 2021 18:01:50
User entered '5'	System	28 Dec 2020 18:31:18
User entered '4'	System	15 Dec 2020 15:55:56
User entered '3'	System	15 Dec 2020 13:59:43
User entered '2'	System	01 Dec 2020 14:34:19
User entered '1'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:24:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
User entered '30/Nov/2020 12:14'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:24:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 14:34:03
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'USA-US070-2020-MRNA-1273-P301000026'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Adam'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Brosz'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered '2444 W. Faidley Ave'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Grand Island'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'NE'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered '68803'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 14:34:03
User entered 'US'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Feb 2021 18:01:50
User entered '5'	System	28 Dec 2020 18:31:18
User entered '4'	System	15 Dec 2020 15:55:56
User entered '3'	System	15 Dec 2020 13:59:43
User entered '2'	System	01 Dec 2020 14:34:19
User entered '1'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:24:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
User entered '01/Dec/2020 09:34'	System	01 Dec 2020 14:34:19

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:24:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 13:59:35
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 14:34:19

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'USA-US070-2020-MRNA-1273-P301000026'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Adam'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Brosz'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered '2444 W. Faidley Ave'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Grand Island'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'NE'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered '68803'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		01 Dec 2020 14:34:03
User entered 'US'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Feb 2021 18:01:50
User entered '5'	System	28 Dec 2020 18:31:18
User entered '4'	System	15 Dec 2020 15:55:56
User entered '3'	System	15 Dec 2020 13:59:43
User entered '2'	System	01 Dec 2020 14:34:19
User entered '1'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:24:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
User entered '15/Dec/2020 08:59'	System	15 Dec 2020 13:59:43

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:24:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		28 Dec 2020 18:30:59
User entered 'I'		15 Dec 2020 13:59:43

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'USA-US070-2020-MRNA-1273-P301000026'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Adam'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Brosz'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered '2444 W. Faidley Ave'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Grand Island'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'NE'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered '68803'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		01 Dec 2020 14:34:03
User entered 'US'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Feb 2021 18:01:50
User entered '5'	System	28 Dec 2020 18:31:18
User entered '4'	System	15 Dec 2020 15:55:56
User entered '3'	System	15 Dec 2020 13:59:43
User entered '2'	System	01 Dec 2020 14:34:19
User entered '1'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:24:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
User entered '15/Dec/2020 10:55'	System	15 Dec 2020 15:55:56

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:24:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		28 Dec 2020 18:30:59
User entered 'I'		15 Dec 2020 15:55:56

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'USA-US070-2020-MRNA-1273-P301000026'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Adam'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Brosz'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered '2444 W. Faidley Ave'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'Grand Island'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'NE'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered '68803'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		01 Dec 2020 14:34:03
User entered 'US'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Feb 2021 18:01:50
User entered '5'	System	28 Dec 2020 18:31:18
User entered '4'	System	15 Dec 2020 15:55:56
User entered '3'	System	15 Dec 2020 13:59:43
User entered '2'	System	01 Dec 2020 14:34:19
User entered '1'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:24:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
User entered '28/Dec/2020 13:31'	System	28 Dec 2020 18:31:18

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:24:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:01:43
DataPoint Verified.		26 Jan 2021 15:24:06
User entered '1'		28 Dec 2020 18:31:18

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.		30 Nov 2020 17:14:21
User entered 'USA-US070-2020-MRNA-1273-P301000026'		30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Yes (Y)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'No (N)'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Adam'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Brosz'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered '2444 W. Faidley Ave'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'Grand Island'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered 'NE'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 17:14:21
User entered '68803'	System	30 Nov 2020 17:14:08

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 15:24:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 14:34:03
User entered 'US'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 16:24:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	22 Feb 2021 18:01:50
User entered '5'	System	28 Dec 2020 18:31:18
User entered '4'	System	15 Dec 2020 15:55:56
User entered '3'	System	15 Dec 2020 13:59:43
User entered '2'	System	01 Dec 2020 14:34:19
User entered '1'	System	30 Nov 2020 17:14:31

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:24:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered '22/Feb/2021 13:01'	System	22 Feb 2021 18:01:50

US3272377

Folder: SAE USA-US070-2020-MRNA-1273-P301000026

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:24:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:16:43
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 18:01:50