

US3402448 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

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US3402448

Form: Participant Creation

Data signed: (b) (4) 27 Apr 2021 00:01:45

Generated On: 09 Jun 2021 17:24:13

[Participant ID](#)

US3402448

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

US3402448

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 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) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 08 Mar 2021 22:47:29

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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) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Condition	EMPHYSEMA
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) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Condition	HYPERCHOLESTERDEMIA
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Condition	DEPRESSION
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 (4)

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	UN MAY 2020
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)	09 FEB 2021
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2021
Stop Year (derived)	2021

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Condition	LEFT KNEE OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Condition	OVERACTIVE BLADDER
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Condition	TOTAL HYSTERECTOMY (EXCESSIVE BLEEDING AND CRAMPING)
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	16:28 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 16:28
Height (<i>xxx.x</i>)	157.5 cm
Weight (<i>xxx.x</i>)	84.4 kg
BMI (<i>xxx.x</i>)	34.02368 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 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: Screening

Form: Childbearing Potential

Data signed: (b) (4) 08 Mar 2021 22:47:29

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Date of assessment (dd MMM yyyy) 21 OCT 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☒
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2001

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 08 Mar 2021 22:47:29

Generated On: 09 Jun 2021 17:24:13

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

FREQUENTLY GOES TO STORES
AND RESTAURANTS

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 08 Mar 2021 22:47:29

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

What was the date of randomization? (dd MMM yyyy) 21 OCT 2020

What was the participant's randomization number? 187792

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

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)	21 OCT 2020
Time of assessment (00:00-23:59)	16:28 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 16:28
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

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)	21 OCT 2020
Time of assessment (00:00-23:59)	18:02 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 18:02
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

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) 21 OCT 2020

What was the treatment time? (00:00-23:59) 17:25 (24 HR)

Treatment Date and Time (derived) 21 OCT 2020 17:25

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	21 OCT 2020
Collection time (<i>00:00-23:59</i>)	18:02 (24 HR)
Collection date and time (derived)	21 OCT 2020 18:02

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Collection date (dd MMM yyyy)			21 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:10	21 OCT 2020 17:10
Nasopharyngeal Swab 2	No		

US3402448

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 18:13

PC Open Date & Time

21 OCT 2020 15:45

PC Close Date & Time

21 OCT 2020 18:15

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	21 OCT 2020 21:14
PC Open Date & Time	21 OCT 2020 21:10
PC Close Date & Time	22 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 19:27

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

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

99.4 °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

23 OCT 2020 13:26

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

98.4 °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

24 OCT 2020 16:44

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 13:14

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

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

26 OCT 2020 16:06

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 16:31

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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

21 OCT 2020 18:14

PC Open Date & Time

21 OCT 2020 15:45

PC Close Date & Time

21 OCT 2020 18:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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

21 OCT 2020 21:15

PC Open Date & Time

21 OCT 2020 21:10

PC Close Date & Time

22 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

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

22 OCT 2020 19:28

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 OCT 2020 13:27

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

24 OCT 2020 16:45

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

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

25 OCT 2020 13:15

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

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

26 OCT 2020 16:07

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

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

27 OCT 2020 16:31

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

21 OCT 2020 17:45

PC Close Date & Time

21 OCT 2020 20:15

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 21:16
PC Open Date & Time	21 OCT 2020 21:10
PC Close Date & Time	22 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

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 ☒

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 19:28
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 13:27
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

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 ☒

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 16:46
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

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

59 of 2110

EAB) (1725)

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 13:16
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 2110

EAB) (1725)

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 16:07
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 2110

EAB) (1725)

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 16:32
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3402448

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402448

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402448

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments COULD NOT REACH SUBJECT.

If Contact Not Made, please provide Comments

US3402448

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

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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US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

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)	13:03 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 13:03
Temperature (xxx.x)	36.4 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

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)	14:11 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 14:11
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3402448

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

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.

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

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) 13:35 (24 HR)

Treatment Date and Time (derived) 16 NOV 2020 13:35

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

US3402448

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 NOV 2020

Collection time (00:00-23:59)

13:23 (24 HR)

Collection date and time (derived)

16 NOV 2020 13:23

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

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	13:26	16 NOV 2020 13:26
Nasopharyngeal Swab 2	No		

US3402448

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp	16 NOV 2020 14:21
PC Open Date & Time	16 NOV 2020 13:55
PC Close Date & Time	16 NOV 2020 16:25

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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 98.0 °F

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

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

PC Time Stamp	17 NOV 2020 04:51
PC Open Date & Time	16 NOV 2020 17:20
PC Close Date & Time	17 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

17 NOV 2020 15:16

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

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

99.2 °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 NOV 2020 16:43

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

98.7 °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

19 NOV 2020 16:13

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 NOV 2020 17:18

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

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

98.8 °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

21 NOV 2020 12:03

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

23 NOV 2020 08:56

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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 14:22

PC Open Date & Time

16 NOV 2020 13:55

PC Close Date & Time

16 NOV 2020 16:25

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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 04:52

PC Open Date & Time

16 NOV 2020 17:20

PC Close Date & Time

17 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

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 15:16

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 NOV 2020 16:43

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

19 NOV 2020 16:14

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

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 NOV 2020 17:19

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

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 12:04

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 NOV 2020 08:57

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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

No ☒

Yes ☐

PC Time stamp	16 NOV 2020 14:22
PC Open Date & Time	16 NOV 2020 13:55
PC Close Date & Time	16 NOV 2020 16:25

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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

No ☒

Yes ☐

PC Time stamp	17 NOV 2020 04:53
PC Open Date & Time	16 NOV 2020 17:20
PC Close Date & Time	17 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

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)

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

Yes <input type="checkbox"/>	
PC Time stamp	17 NOV 2020 15:17
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

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 ☒

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

Yes <input type="checkbox"/>	
PC Time stamp	18 NOV 2020 16:44
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

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 ☒

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

Yes <input type="checkbox"/>	
PC Time stamp	19 NOV 2020 16:15
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

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 ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

Yes <input type="checkbox"/>	
PC Time stamp	20 NOV 2020 17:20
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

Yes <input type="checkbox"/>	
PC Time stamp	21 NOV 2020 12:05
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

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 ☒

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

Yes <input type="checkbox"/>	
PC Time stamp	23 NOV 2020 08:58
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3402448

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402448

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402448

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402448

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:33:02

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 DEC 2020
Time of assessment (00:00-23:59)	13:18 (24 HR)
Vital Signs Date and Time (derived)	11 DEC 2020 13:18
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402448

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

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.

US3402448

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 DEC 2020

Collection time (00:00-23:59)

13:23 (24 HR)

Collection date and time (derived)

11 DEC 2020 13:23

US3402448

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:33:55

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 01:48:22
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 DEC 2020 08:26:28
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 JAN 2021 00:47:51

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 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	08 JAN 2021 12:46:27
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 19:14:40
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 JAN 2021 17:02:58
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 14:46:27

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 18:39:25

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 16:51:31
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 02:45:55
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 00:25:59

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

05 MAR 2021 10:56:53

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 11:42:08
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 MAR 2021 18:07:42
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 APR 2021 19:10:48
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

12 APR 2021 00:03:19

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 <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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2021 00:01
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Patient Cloud Close Date & Time	27 APR 2021 23:59
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US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

30 APR 2021 23:51:48

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 <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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 <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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2021 00:01
Patient Cloud Close Date & Time	28 SEP 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 <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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 OCT 2021 00:01
Patient Cloud Close Date & Time	02 NOV 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JAN 2022 00:01
Patient Cloud Close Date & Time	11 JAN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐
Yes ☐

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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°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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐ Yes ☐

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

Patient Cloud Open Date & Time	26 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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°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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

[Patient Cloud Open Date & Time](#)

25 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2022 00:01
Patient Cloud Close Date & Time	06 DEC 2022 23:59

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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°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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:24:13

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		05 MAR 2021 10:57:17

US3402448

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:35:25

Generated On: 09 Jun 2021 17:24:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402448

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:35:25

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 27 Apr 2021 00:01:47

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 27 Apr 2021 00:01:47

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 27 Apr 2021 00:01:47

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 27 Apr 2021 00:01:47

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 27 Apr 2021 00:01:47

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 27 Apr 2021 00:01:47

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3402448

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3402448

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

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.

US3402448

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<input type="text"/>
Collection time (<i>00:00-23:59</i>)	<input type="text"/>
Collection date and time (derived)	<input type="text"/>

US3402448

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402448

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:13

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"/>

US3402448

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:24:13

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402448

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

Form: Visit Date

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

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

Visit date (dd MMM yyyy)	22 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3402448

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

Form: Unblinding

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3402448

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

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

US3402448

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	08:56 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 08:56
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3402448

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	10:01 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 10:01
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)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3402448

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

Form: Physical Examination

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 JAN 2021

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

US3402448

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

Form: Exposure

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 09:30 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 09:30

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3402448

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00-23:59)	08:35 (24 HR)
Collection date and time (derived)	22 JAN 2021 08:35

US3402448

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	08:35
Collection Date and Time (derived)	22 JAN 2021 08:35

US3402448

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

Form: Continuing

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 27 Apr 2021 00:01:47

Generated On: 09 Jun 2021 17:24:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402448

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 27 Apr 2021 00:01:47

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	08:16 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 08:16
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	09:16 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 09:16
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3402448

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3402448

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 08:45 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 08:45

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

US3402448

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 27 Apr 2021 00:01:47

Generated On: 09 Jun 2021 17:24:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402448

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 27 Apr 2021 00:01:47

Generated On: 09 Jun 2021 17:24:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402448

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3402448

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

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.

US3402448

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 MAR 2021
Collection time (00:00-23:59)	14:11 (24 HR)
Collection date and time (derived)	16 MAR 2021 14:11

US3402448

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:53:27

Generated On: 09 Jun 2021 17:24:13

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Apr 2021 00:01:45

Generated On: 09 Jun 2021 17:24:13

AEID	USA-US059-2020-MRNA-1273-P30 1000017
Adverse event	WORSENING OF EMPHYSEMA
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)	09 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)	11 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	11 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Apr 2021 00:01:45

Generated On: 09 Jun 2021 17:24:13

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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:	SUBJECT WAS SENT HOME ON 2 LITERS OF CONTINUOUS OXYGEN
Narrative	AWAITING MEDICAL RECORDS
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

US3402448

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 27 Apr 2021 00:01:45

Generated On: 09 Jun 2021 17:24:13

AEID

Adverse event

SINUSITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

29 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 27 Apr 2021 00:01:45

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:45:52

Generated On: 09 Jun 2021 17:24:13

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

Yes ☒

No ☐

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

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication LEFT KNEE OSTEOARTHRITIS

Dose per administration 200

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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US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTERDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

	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 2006	
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"/>

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

Name of Medication TOPIRAMATE

Prophylaxis Yes ☐
No ☒

Indication SCHIZOAFFECTIVE DISORDER

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

Name of Medication OLANZAPINE

Prophylaxis Yes ☐
No ☒

Indication SCHIZOAFFECTIVE DISORDER

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

	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"/>

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

Name of Medication OXYBUTININ

Prophylaxis Yes ☐
No ☒

Indication OVERACTIVE BLADDER

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)

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

Name of Medication LOSARTAN POTASSIUM

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

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

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

Name of Medication PANTOPRAZOLE

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 (8)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

	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 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF EMPHYSEMA

Dose per administration 2

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

If dose unit is Other, specify LITERS PER MINUTE

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 CONTINUOUSLY

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication PAIN CONTROL FOR AFTER
HIATAL HERNIA SURGERY

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

	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)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication SINUSITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:45:50

Generated On: 09 Jun 2021 17:24:13

	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)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 MAR 2021	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402448

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:45:52

Generated On: 09 Jun 2021 17:24:13

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402448

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 23:45:52

Generated On: 09 Jun 2021 17:24:13

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
9 FEB 2021	HIATAL HERNIA REPAIR	Medical History	

US3402448

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:24:13

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 ☐

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

SAEID	USA-US059-2020-MRNA-1273-P301000017
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

SAEID	USA-US059-2020-MRNA-1273-P301000017
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	17/NOV/2020 08:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 27 Apr 2021 00:01:46

Generated On: 09 Jun 2021 17:24:13

SAEID	USA-US059-2020-MRNA-1273-P301000017
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	25/NOV/2020 15:35
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

US3402448 (Prod: Meridian Clinical Research, LLC)

US3402448

Form: Participant Creation

Generated On: 09 Jun 2021 17:24:13

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'US3402448'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 21:08:26

US3402448

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:12

US3402448

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '21 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 21:08:27

US3402448

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:12

US3402448

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'SCRN'	System	21 Oct 2020 22:10:12

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1954. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 11:07:32
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1954. Please clarify the subject's Year of Birth and update as appropriate.' answered with 'PATIENTS DATE OF BIRTH IS 1954. THIS HAS ALREADY BEEN SENT BY OUR LAB TECH TO HAVE CORRECTED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	02 Nov 2020 12:46:01
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1954. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 17:25:24
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 21:08:28

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '66'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'YEARS'	System	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '66'	System	21 Oct 2020 22:11:07
User entered empty.	System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Female. Please clarify the subject's Sex and update if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 10:28:25
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Female. Please clarify the subject's Sex and update if appropriate.' answered with 'THIS PATIENT IS A FEMALE. THE LAB HAS ALREADY SENT THE INFORMATION TO HAVE IT CORRECTED ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Oct 2020 19:55:20
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Female. Please clarify the subject's Sex and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:45:49
User entered 'Female (F)'	(b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:13

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:32

US3402448

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:13

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 22:11:07
User entered '21 Oct 2020' reason for change: Data Entry Error	System	21 Oct 2020 22:11:07
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 22:10:58
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Oct 2020'	System	21 Oct 2020 22:11:07
User entered empty.	System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2020'	System	21 Oct 2020 22:11:07
User entered empty.	System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:13

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Amendment 4 (4)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:13

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:13

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:13

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:13

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 21:08:27

US3402448

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:13

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'I'	System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:09:56

US3402448

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:24:13

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:56:57
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 22:59:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 22:59:43
Data point term sent to Coder	System	21 Oct 2020 22:58:16
User entered 'EMPHYSEMA'	Tammy Kohn (b) (4)	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN UNK 2016'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:57:23
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 23:13:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	21 Oct 2020 23:13:34
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	21 Oct 2020 22:57:23
	Tammy Kohn (b) (4)	21 Oct 2020 22:57:23
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:57:23
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:57:23
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Jan 2016'	System	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2016'	System	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 22:57:23

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 22:59:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 22:59:43
Data point term sent to Coder	System	21 Oct 2020 22:58:17
User entered 'HYPERCHOLESTERDEMIA'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN UNK 2006'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:58:04
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Jan 2006'	System	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2006'	System	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 22:58:04

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	(b) (4) (b) (4)	21 Oct 2020 23:00:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:00:45
Data point term sent to Coder	(b) (4)	21 Oct 2020 22:59:19
User entered 'DEPRESSION'	System	21 Oct 2020 22:58:22
	Tammy Kohn (b) (4)	
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN UNK 1998'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:58:22
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:58:22
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:58:22
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Jan 1998'	System	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '1998'	System	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 22:58:22

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User coded data point as SOC: Psychiatric disorders, HLG: Schizophrenia and other psychotic disorders, HLT: Schizoaffective and schizophreniform disorders, PT: Schizoaffective disorder, LLT: Schizoaffective disorder - version MedDRA\\23.0.	(b) (4) (b) (4)	21 Oct 2020 23:01:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:01:48
Data point term sent to Coder	(b) (4) System	21 Oct 2020 23:00:22
User entered 'SCHIZOAFFECTIVE DISORDER'	Tammy Kohn (b) (4)	21 Oct 2020 23:00:12
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN UNK 2010'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:00:12
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:00:12
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Jan 2010'	System	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2010'	System	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 23:00:12

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
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.	(b) (4) (b) (4) Coder Import (b) (4)	21 Oct 2020 23:02:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:02:35
Data point term sent to Coder	System	21 Oct 2020 23:01:23
User entered 'HYPERTENSION'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN UNK 2008'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Jan 2008'	System	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2008'	System	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 23:00:38

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
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.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 23:02:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:02:35
Data point term sent to Coder	System	21 Oct 2020 23:01:23
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN UNK 2006'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:01:07
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:01:07
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Jan 2006'	System	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2006'	System	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 23:01:07

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	21 Oct 2020 23:02:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:02:35
Data point term sent to Coder	(b) (4)	21 Oct 2020 23:02:23
User entered 'HIATAL HERNIA'	System Tammy Kohn (b) (4)	21 Oct 2020 23:01:39
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN May 2020'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	23 Feb 2021 21:22:50
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	21 Oct 2020 23:01:39
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '09 Feb 2021' reason for change: Data Entry Error	(b) (4)	23 Feb 2021 21:22:50
User entered empty.	Tammy Kohn (b) (4)	21 Oct 2020 23:01:39
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'May 2020'	System	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2020'	System	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Feb 2021'	System	23 Feb 2021 21:22:50
User entered empty.	System	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2021'	System	23 Feb 2021 21:22:50
User entered empty.	System	21 Oct 2020 23:01:39

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User closed query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 10:39:02
Query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 14:05:38
User opened query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 10:11:20
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy L knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:02:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:02:36
Data point term sent to Coder	System	21 Oct 2020 23:02:23
User entered 'LEFT KNEE ARTHROSCOPY'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN Apr 2020'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:06
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:06
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Jan 2021 14:05:32
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	21 Oct 2020 23:02:06
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN Apr 2020' reason for change: Data Entry Error	(b) (4)	14 Jan 2021 14:05:32
User entered empty.	Tammy Kohn (b) (4)	21 Oct 2020 23:02:06
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:06
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Apr 2020'	System	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2020'	System	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Apr 2020'	System	14 Jan 2021 14:05:32
User entered empty.	System	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2020'	System	14 Jan 2021 14:05:32
User entered empty.	System	21 Oct 2020 23:02:06

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 10:39:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 14:07:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 14:07:54
Data point term sent to Coder	System	14 Jan 2021 14:06:48
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 14:06:13
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 14:06:06
User entered 'LEFT KNEE OSTEOARTHRTITIS' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 14:06:06
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 10:11:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:04:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:04:38
Data point term sent to Coder	System	21 Oct 2020 23:03:27

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:13

[Condition](#)

Audit	User	Time (GMT)
User entered 'LEFT KNEE ARTHRITIS'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN UNK 2018'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:37
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:37
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Jan 2018'	System	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2018'	System	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 23:02:37

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:04:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 23:04:38
Data point term sent to Coder	System	21 Oct 2020 23:03:26
User entered 'OVERACTIVE BLADDER'	Tammy Kohn (b) (4)	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN UNK 2005'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:58
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:02:58
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Jan 2005'	System	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2005'	System	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered empty.	System	21 Oct 2020 23:02:58

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:36:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:36:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:47:29
User closed query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 10:39:42
Data point term sent to Coder	System	14 Jan 2021 14:08:49
Query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 14:08:01
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 14:07:53
User entered 'TOTAL HYSTERECTOMY (EXCESSIVE BLEEDING AND CRAMPING)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 14:07:53
User opened query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 10:12:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:04:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:04:37
Data point term sent to Coder	System	21 Oct 2020 23:03:28

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:13

[Condition](#)

Audit	User	Time (GMT)
User entered 'TOTAL HYSTERECTOMY'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN UNK 2001'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:03:24
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Jan 2021 14:07:53
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	21 Oct 2020 23:03:24
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN UNK 2001' reason for change:	(b) (4)	
Data Entry Error	Tammy Kohn (b) (4)	14 Jan 2021 14:07:53
User entered empty.	(b) (4)	
	Tammy Kohn (b) (4)	21 Oct 2020 23:03:24
	(b) (4)	

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Jan 2001'	System	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2001'	System	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'Jan 2001'	System	14 Jan 2021 14:07:53
User entered empty.	System	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '2001'	System	14 Jan 2021 14:07:53
User entered empty.	System	21 Oct 2020 23:03:24

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '21 Oct 2020'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '16:28'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '21 Oct 2020 16:28'	System	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '157.5' cm	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:14
DataPoint set to visible.	(b) (4) System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '84.4' kg	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:14
DataPoint set to visible.	(b) (4) System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered '34.02368'	System	21 Oct 2020 23:05:14
DataPoint set to visible.	System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'kg/m2'	System	21 Oct 2020 23:05:14
DataPoint set to visible.	System	21 Oct 2020 22:10:58

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User closed query 'Per CDM: As per CCGs page 17-18, for Screening and Visit 1 on the same day, 'ND-NOT DONE'. should be recorded for Temperature (without unit), Pulse, Respiratory rate, Systolic BP and Diastolic BP. Please update accordingly. Note: Route of measurement should be left blank' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 06:12:34
Query 'Per CDM: As per CCGs page 17-18, for Screening and Visit 1 on the same day, 'ND-NOT DONE'. should be recorded for Temperature (without unit), Pulse, Respiratory rate, Systolic BP and Diastolic BP. Please update accordingly. Note: Route of measurement should be left blank' answered with 'data updated to nd' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	24 Dec 2020 13:04:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	24 Dec 2020 13:03:34
User opened query 'Per CDM: As per CCGs page 17-18, for Screening and Visit 1 on the same day, 'ND-NOT DONE'. should be recorded for Temperature (without unit), Pulse, Respiratory rate, Systolic BP and Diastolic BP. Please update accordingly. Note: Route of measurement should be left blank' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 06:58:54
User entered '36.8' C	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty; reason for change Data Entry Error	(b) (4)	24 Dec 2020 13:03:34
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	21 Oct 2020 23:05:14
	(b) (4)	

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Dec 2020 13:03:34
User entered '74'	Tammy Kohn (b) (4)	21 Oct 2020 23:05:14
	(b) (4)	

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'bpm'	System	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Dec 2020 13:03:34
User entered '18'	Tammy Kohn (b) (4)	21 Oct 2020 23:05:14
	(b) (4)	

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'breaths/min'	System	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Dec 2020 13:03:34
User entered '128'	Tammy Kohn (b) (4)	21 Oct 2020 23:05:14
	(b) (4)	

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'mmHg'	System	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	24 Dec 2020 13:03:34
User entered '80'	Tammy Kohn (b) (4)	21 Oct 2020 23:05:14
	(b) (4)	

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User entered 'mmHg'	System	21 Oct 2020 23:05:14

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25

US3402448

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25

US3402448

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:20
	(b) (4)	

US3402448

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '21 Oct 2020'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:20
	(b) (4)	

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '21 Oct 2020'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:13

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:52

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:13

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Surgically sterile (SURGICALLY STERILE)'	Tammy Kohn (b) (4)	21 Oct 2020 23:05:52

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:13

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:13

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'UN UNK 2001'	(b) (4) Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:13

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:13

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:13

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:05:52

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

[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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

[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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:13
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

[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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

[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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:13
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'No (N)'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:13
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'FREQUENTLY GOES TO STORES AND RESTAURANTS'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered 'I'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

[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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:13
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

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 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:13
	(b) (4)	

US3402448

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:03:25
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:47:29
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:13
	(b) (4)	

US3402448

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:09:28

US3402448

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:09:28

US3402448

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:09:28

US3402448

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'VISIT1'	System	21 Oct 2020 22:09:28

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '21 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 21:18:34

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '187792'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 21:18:34

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 21:18:34

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:13

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)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:50

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:13

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)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'No (N)'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:50

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:50

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'No (N)'	Tammy Kohn (b) (4)	21 Oct 2020 23:08:50

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:13

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:08:50

US3402448

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:13

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'No (N)'	(b) (4)	
	Tammy Kohn (b) (4)	21 Oct 2020 23:08:50
	(b) (4)	
DataPoint set to visible.	System	21 Oct 2020 22:10:58

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered missing code ND - Not Done.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered missing code ND - Not Done.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered missing code ND - Not Done.	Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered missing code ND - Not Done.	Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '21 Oct 2020'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	22 Oct 2020 00:26:49
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	21 Oct 2020 23:11:26
User entered '16:28'	Tammy Kohn (b) (4)	21 Oct 2020 23:11:26
	(b) (4)	

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered '21 Oct 2020 16:28'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '36.8' C	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '74'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'bpm'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '18'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'breaths/min'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '128'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'mmHg'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '80'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'mmHg'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered missing code ND - Not Done.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered missing code ND - Not Done.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '21 Oct 2020'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '18:02'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered '21 Oct 2020 18:02'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '37.0' C	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '82'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'bpm'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '18'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'breaths/min'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '128'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'mmHg'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '82'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'mmHg'	System	21 Oct 2020 23:11:26

US3402448

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'No (N)'	(b) (4)	21 Oct 2020 23:11:40
	Tammy Kohn (b) (4)	
	(b) (4)	

US3402448

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:11:40

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

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)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'MRNA-1273 OR PLACEBO'	System	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered '17:25' reason for change: Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	22 Oct 2020 00:26:49
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Oct 2020 22:12:01
User entered '15:25' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 22:12:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Oct 2020 22:11:47
User entered '15:' (non-conformant).	(b) (4), (b) (6)	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered '21 Oct 2020 17:25'	System	22 Oct 2020 00:26:49
User entered '21 Oct 2020 15:25'	System	21 Oct 2020 22:12:01
User entered '21 Oct 2020 15:' (non-conformant).	System	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'ONCE'	System	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'INTRAMUSCULAR'	System	21 Oct 2020 22:11:47

US3402448

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:12:12

US3402448

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered '21 Oct 2020'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:12:12

US3402448

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered '18:02'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:12:12
	(b) (4)	

US3402448

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered '21 Oct 2020 18:02'	System	21 Oct 2020 23:12:12

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:24:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered '21 Oct 2020'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered '17:10'	Tammy Kohn (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered '21 Oct 2020 17:10'	System	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered empty.	System	21 Oct 2020 23:13:10

US3402448

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	21 Oct 2020 23:13:15

US3402448

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'I'	System	21 Oct 2020 23:13:15

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:13:21', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'df92be9e-cc17-4d33-85ff-cb4409eb605f'	System	21 Oct 2020 22:14:01
User entered 'Yes (Y)'	System	21 Oct 2020 22:14:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:13:32', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'df92be9e-cc17-4d33-85ff-cb4409eb605f' User entered '98.6'	System	21 Oct 2020 22:14:01
	System	21 Oct 2020 22:14:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:13:49', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'df92be9e-cc17-4d33-85ff-cb4409eb605f'	System	21 Oct 2020 22:14:01
User entered 'No (N)'	System	21 Oct 2020 22:14:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:13:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'df92be9e-cc17-4d33-85ff-cb4409eb605f' User entered '21 Oct 2020 18:13'	System	21 Oct 2020 22:14:01
	System	21 Oct 2020 22:14:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Oct 2020 15:45'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Oct 2020 18:15'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:12:25', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f92f97a-3c6a-4b4c-bc1a-bc3aa0c2ff50'	System	22 Oct 2020 01:14:22
User entered 'Yes (Y)'	System	22 Oct 2020 01:14:22

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:12:38', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f92f97a-3c6a-4b4c-bc1a-bc3aa0c2ff50'	System	22 Oct 2020 01:14:22
User entered '98.6'	System	22 Oct 2020 01:14:22

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:12:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f92f97a-3c6a-4b4c-bc1a-bc3aa0c2ff50'	System	22 Oct 2020 01:14:22
User entered 'No (N)'	System	22 Oct 2020 01:14:22

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:14:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f92f97a-3c6a-4b4c-bc1a-bc3aa0c2ff50'	System	22 Oct 2020 01:14:22
User entered '21 Oct 2020 21:14'	System	22 Oct 2020 01:14:22

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Oct 2020 21:10'	System	22 Oct 2020 00:26:49
User entered '21 Oct 2020 19:10'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 2'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:25:25', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '125ab44b-d2f4-483f-be43-76b259a67bc0'	System	22 Oct 2020 23:27:29
User entered 'Yes (Y)'	System	22 Oct 2020 23:27:29

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:25:41', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '125ab44b-d2f4-483f-be43-76b259a67bc0'	System	22 Oct 2020 23:27:29
User entered '98.9'	System	22 Oct 2020 23:27:29

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:25:46', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '125ab44b-d2f4-483f-be43-76b259a67bc0'	System	22 Oct 2020 23:27:29
User entered 'No (N)'	System	22 Oct 2020 23:27:29

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:27:26', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '125ab44b-d2f4-483f-be43-76b259a67bc0'	System	22 Oct 2020 23:27:29
User entered '22 Oct 2020 19:27'	System	22 Oct 2020 23:27:29

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 3'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:25:18', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'aa782f90-ccad-49ac-a7ed-21180d98ed69'	System	23 Oct 2020 17:26:30
User entered 'Yes (Y)'	System	23 Oct 2020 17:26:30

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:25:26', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'aa782f90-ccad-49ac-a7ed-21180d98ed69'	System	23 Oct 2020 17:26:30
User entered '99.4'	System	23 Oct 2020 17:26:30

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:25:32', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'aa782f90-ccad-49ac-a7ed-21180d98ed69'	System	23 Oct 2020 17:26:30
User entered 'No (N)'	System	23 Oct 2020 17:26:30

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:26:26', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'aa782f90-ccad-49ac-a7ed-21180d98ed69'	System	23 Oct 2020 17:26:30
User entered '23 Oct 2020 13:26'	System	23 Oct 2020 17:26:30

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 4'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:43:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd86fb2bf-bfec-49d0-837d-7e8b02867661'	System	24 Oct 2020 20:44:23
User entered 'Yes (Y)'	System	24 Oct 2020 20:44:23

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:43:59', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd86fb2bf-bfec-49d0-837d-7e8b02867661'	System	24 Oct 2020 20:44:23
User entered '98.4'	System	24 Oct 2020 20:44:23

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:44:03', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd86fb2bf-bfec-49d0-837d-7e8b02867661'	System	24 Oct 2020 20:44:23
User entered 'No (N)'	System	24 Oct 2020 20:44:23

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:44:21', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd86fb2bf-bfec-49d0-837d-7e8b02867661'	System	24 Oct 2020 20:44:23
User entered '24 Oct 2020 16:44'	System	24 Oct 2020 20:44:23

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 5'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:13:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'fbaab43c-bb61-4055-abfd-f5a9d90fd199'	System	25 Oct 2020 17:14:50
User entered 'Yes (Y)'	System	25 Oct 2020 17:14:50

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:13:30', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'fbaab43c-bb61-4055-abfd-f5a9d90fd199'	System	25 Oct 2020 17:14:50
User entered '98.0'	System	25 Oct 2020 17:14:50

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:13:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'fbaab43c-bb61-4055-abfd-f5a9d90fd199'	System	25 Oct 2020 17:14:50
User entered 'No (N)'	System	25 Oct 2020 17:14:50

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:14:47', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'fbaab43c-bb61-4055-abfd-f5a9d90fd199'	System	25 Oct 2020 17:14:50
User entered '25 Oct 2020 13:14'	System	25 Oct 2020 17:14:50

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 6'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:02', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e2709795-1236-455d-8f5e-0c29776c5894'	System	26 Oct 2020 20:06:39
User entered 'Yes (Y)'	System	26 Oct 2020 20:06:39

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e2709795-1236-455d-8f5e-0c29776c5894' User entered '98.5'	System	26 Oct 2020 20:06:39

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:15', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e2709795-1236-455d-8f5e-0c29776c5894'	System	26 Oct 2020 20:06:39
User entered 'No (N)'	System	26 Oct 2020 20:06:39

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:36', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e2709795-1236-455d-8f5e-0c29776c5894'	System	26 Oct 2020 20:06:39
User entered '26 Oct 2020 16:06'	System	26 Oct 2020 20:06:39

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 7'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:30:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4cbdfb4e-c36b-4a3c-a8bd-164ad8eb3a4a'	System	27 Oct 2020 20:31:13
User entered 'Yes (Y)'	System	27 Oct 2020 20:31:13

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:01', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4cbdfb4e-c36b-4a3c-a8bd-164ad8eb3a4a'	System	27 Oct 2020 20:31:13
User entered '98.2'	System	27 Oct 2020 20:31:13

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:05', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4cbdfb4e-c36b-4a3c-a8bd-164ad8eb3a4a'	System	27 Oct 2020 20:31:13
User entered 'No (N)'	System	27 Oct 2020 20:31:13

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4cbdfb4e-c36b-4a3c-a8bd-164ad8eb3a4a'	System	27 Oct 2020 20:31:13
User entered '27 Oct 2020 16:31'	System	27 Oct 2020 20:31:13

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:14:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '49f7b1bf-d32d-4fc0-8d86-7a2de19086a6'	System	21 Oct 2020 22:15:03
User entered 'None (1)'	System	21 Oct 2020 22:15:03

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:14:30', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '49f7b1bf-d32d-4fc0-8d86-7a2de19086a6'	System	21 Oct 2020 22:15:03
User entered 'No (N)'	System	21 Oct 2020 22:15:03

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:14:40', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '49f7b1bf-d32d-4fc0-8d86-7a2de19086a6'	System	21 Oct 2020 22:15:03
User entered 'No (N)'	System	21 Oct 2020 22:15:03

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:14:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '49f7b1bf-d32d-4fc0-8d86-7a2de19086a6'	System	21 Oct 2020 22:15:03
User entered 'None (1)'	System	21 Oct 2020 22:15:03

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T18:14:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '49f7b1bf-d32d-4fc0-8d86-7a2de19086a6'	System	21 Oct 2020 22:15:03
User entered '21 Oct 2020 18:14'	System	21 Oct 2020 22:15:03

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Oct 2020 15:45'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Oct 2020 18:15'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:14:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '285fb6c3-8c25-4b29-be90-8cf38b5616ed'	System	22 Oct 2020 01:15:27
User entered 'None (1)'	System	22 Oct 2020 01:15:27

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:14:49', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '285fb6c3-8c25-4b29-be90-8cf38b5616ed'	System	22 Oct 2020 01:15:27
User entered 'No (N)'	System	22 Oct 2020 01:15:27

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:14:57', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '285fb6c3-8c25-4b29-be90-8cf38b5616ed'	System	22 Oct 2020 01:15:27
User entered 'No (N)'	System	22 Oct 2020 01:15:27

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:15:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '285fb6c3-8c25-4b29-be90-8cf38b5616ed'	System	22 Oct 2020 01:15:27
User entered 'None (1)'	System	22 Oct 2020 01:15:27

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:15:21', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '285fb6c3-8c25-4b29-be90-8cf38b5616ed'	System	22 Oct 2020 01:15:27
User entered '21 Oct 2020 21:15'	System	22 Oct 2020 01:15:27

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Oct 2020 21:10'	System	22 Oct 2020 00:26:49
User entered '21 Oct 2020 19:10'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 2'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:27:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '20929518-aeec-4443-8d1a-3ad1d664685b'	System	22 Oct 2020 23:28:15
User entered 'None (1)'	System	22 Oct 2020 23:28:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:27:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '20929518-aeec-4443-8d1a-3ad1d664685b'	System	22 Oct 2020 23:28:15
User entered 'No (N)'	System	22 Oct 2020 23:28:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:27:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '20929518-aeec-4443-8d1a-3ad1d664685b'	System	22 Oct 2020 23:28:15
User entered 'No (N)'	System	22 Oct 2020 23:28:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:01', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '20929518-aeec-4443-8d1a-3ad1d664685b'	System	22 Oct 2020 23:28:15
User entered 'None (1)'	System	22 Oct 2020 23:28:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '20929518-aeec-4443-8d1a-3ad1d664685b'	System	22 Oct 2020 23:28:15
User entered '22 Oct 2020 19:28'	System	22 Oct 2020 23:28:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 3'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:26:37', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'cb7f71c1-2e45-47e8-a5eb-b33a1e1f9432'	System	23 Oct 2020 17:27:09
User entered 'None (1)'	System	23 Oct 2020 17:27:09

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:26:42', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'cb7f71c1-2e45-47e8-a5eb-b33a1e1f9432'	System	23 Oct 2020 17:27:09
User entered 'No (N)'	System	23 Oct 2020 17:27:09

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:26:47', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'cb7f71c1-2e45-47e8-a5eb-b33a1e1f9432'	System	23 Oct 2020 17:27:09
User entered 'No (N)'	System	23 Oct 2020 17:27:09

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:26:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'cb7f71c1-2e45-47e8-a5eb-b33a1e1f9432'	System	23 Oct 2020 17:27:09
User entered 'None (1)'	System	23 Oct 2020 17:27:09

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:06', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'cb7f71c1-2e45-47e8-a5eb-b33a1e1f9432'	System	23 Oct 2020 17:27:09
User entered '23 Oct 2020 13:27'	System	23 Oct 2020 17:27:09

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 4'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:44:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f12a40b-731b-48de-be9b-3857c6cab8dd'	System	24 Oct 2020 20:45:31
User entered 'None (1)'	System	24 Oct 2020 20:45:31

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:44:49', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f12a40b-731b-48de-be9b-3857c6cab8dd'	System	24 Oct 2020 20:45:31
User entered 'No (N)'	System	24 Oct 2020 20:45:31

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f12a40b-731b-48de-be9b-3857c6cab8dd'	System	24 Oct 2020 20:45:31
User entered 'No (N)'	System	24 Oct 2020 20:45:31

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:21', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f12a40b-731b-48de-be9b-3857c6cab8dd'	System	24 Oct 2020 20:45:31
User entered 'None (1)'	System	24 Oct 2020 20:45:31

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:28', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3f12a40b-731b-48de-be9b-3857c6cab8dd'	System	24 Oct 2020 20:45:31
User entered '24 Oct 2020 16:45'	System	24 Oct 2020 20:45:31

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 5'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0bc93bf7-a078-42e3-92bf-3903dbb2bf03'	System	25 Oct 2020 17:15:30
User entered 'None (1)'	System	25 Oct 2020 17:15:30

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:05', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0bc93bf7-a078-42e3-92bf-3903dbb2bf03'	System	25 Oct 2020 17:15:30
User entered 'No (N)'	System	25 Oct 2020 17:15:30

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:08', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0bc93bf7-a078-42e3-92bf-3903dbb2bf03'	System	25 Oct 2020 17:15:30
User entered 'No (N)'	System	25 Oct 2020 17:15:30

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:18', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0bc93bf7-a078-42e3-92bf-3903dbb2bf03'	System	25 Oct 2020 17:15:30
User entered 'None (1)'	System	25 Oct 2020 17:15:30

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:26', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0bc93bf7-a078-42e3-92bf-3903dbb2bf03'	System	25 Oct 2020 17:15:30
User entered '25 Oct 2020 13:15'	System	25 Oct 2020 17:15:30

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 6'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '38636184-92e1-4e63-b189-7f3f83cc2897'	System	26 Oct 2020 20:07:17
User entered 'None (1)'	System	26 Oct 2020 20:07:17

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:54', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '38636184-92e1-4e63-b189-7f3f83cc2897'	System	26 Oct 2020 20:07:17
User entered 'No (N)'	System	26 Oct 2020 20:07:17

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:06:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '38636184-92e1-4e63-b189-7f3f83cc2897'	System	26 Oct 2020 20:07:17
User entered 'No (N)'	System	26 Oct 2020 20:07:17

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:03', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '38636184-92e1-4e63-b189-7f3f83cc2897'	System	26 Oct 2020 20:07:17
User entered 'None (1)'	System	26 Oct 2020 20:07:17

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '38636184-92e1-4e63-b189-7f3f83cc2897'	System	26 Oct 2020 20:07:17
User entered '26 Oct 2020 16:07'	System	26 Oct 2020 20:07:17

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 7'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:17', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e96248ae-b7ee-4c15-86a2-e7515fc0b99f'	System	27 Oct 2020 20:32:15
User entered 'None (1)'	System	27 Oct 2020 20:32:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:20', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e96248ae-b7ee-4c15-86a2-e7515fc0b99f'	System	27 Oct 2020 20:32:15
User entered 'No (N)'	System	27 Oct 2020 20:32:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:41', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e96248ae-b7ee-4c15-86a2-e7515fc0b99f'	System	27 Oct 2020 20:32:15
User entered 'No (N)'	System	27 Oct 2020 20:32:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e96248ae-b7ee-4c15-86a2-e7515fc0b99f'	System	27 Oct 2020 20:32:15
User entered 'None (1)'	System	27 Oct 2020 20:32:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:31:56', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e96248ae-b7ee-4c15-86a2-e7515fc0b99f' User entered '27 Oct 2020 16:31'	System	27 Oct 2020 20:32:15
	System	27 Oct 2020 20:32:15

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Oct 2020 17:45'	System	22 Oct 2020 00:26:49
User entered '21 Oct 2020 15:45'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Oct 2020 20:15'	System	22 Oct 2020 00:26:49
User entered '21 Oct 2020 18:15'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:15:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa' User entered 'None (0)'	System	22 Oct 2020 01:16:52
	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:06', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa'	System	22 Oct 2020 01:16:52
User entered 'None (0)'	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:15', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa' User entered 'None (0)'	System	22 Oct 2020 01:16:52
	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa' User entered 'None (0)'	System	22 Oct 2020 01:16:52
	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:24', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa' User entered 'None (0)'	System	22 Oct 2020 01:16:52
	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:28', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa' User entered 'None (0)'	System	22 Oct 2020 01:16:52
	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:31', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa'	System	22 Oct 2020 01:16:52
User entered 'No (N)'	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-21T21:16:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'da685198-b910-4a5c-b154-e394b09747fa'	System	22 Oct 2020 01:16:52
User entered '21 Oct 2020 21:16'	System	22 Oct 2020 01:16:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Oct 2020 21:10'	System	22 Oct 2020 00:26:49
User entered '21 Oct 2020 19:10'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 2'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:20', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'None (0)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:27', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'None (0)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:31', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'None (0)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'None (0)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:40', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'None (0)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'None (0)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered 'No (N)'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-22T19:28:57', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e9098feb-4bdd-4dd6-bfdf-197dca036939'	System	22 Oct 2020 23:29:00
User entered '22 Oct 2020 19:28'	System	22 Oct 2020 23:29:00

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 3'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:14', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc'	System	23 Oct 2020 17:27:52
User entered 'None (0)'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc'	System	23 Oct 2020 17:27:52
User entered 'None (0)'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:23', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc' User entered 'None (0)'	System	23 Oct 2020 17:27:52
	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:28', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc' User entered 'None (0)'	System	23 Oct 2020 17:27:52
	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:31', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc'	System	23 Oct 2020 17:27:52
User entered 'None (0)'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc'	System	23 Oct 2020 17:27:52
User entered 'None (0)'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:40', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc'	System	23 Oct 2020 17:27:52
User entered 'No (N)'	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-23T13:27:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1747e839-6eb4-4f94-9e0c-9e7fb2240efc' User entered '23 Oct 2020 13:27'	System	23 Oct 2020 17:27:52
	System	23 Oct 2020 17:27:52

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 4'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:36', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'None (0)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:49', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'No interference with activity (1)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:53', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'None (0)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:45:57', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'None (0)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:46:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'None (0)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:46:02', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'None (0)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:46:05', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered 'No (N)'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-24T16:46:14', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '47c19f7e-9c17-4bb3-9306-66fe83fbada4'	System	24 Oct 2020 20:46:17
User entered '24 Oct 2020 16:46'	System	24 Oct 2020 20:46:17

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 5'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:34', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered 'None (0)'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered 'None (0)'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b' User entered 'None (0)'	System	25 Oct 2020 17:16:07
	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b' User entered 'None (0)'	System	25 Oct 2020 17:16:07
	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b' User entered 'None (0)'	System	25 Oct 2020 17:16:07
	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:54', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered 'None (0)'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:15:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered 'No (N)'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-25T13:16:04', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e09af169-0646-4eeb-a467-35ab95cba33b'	System	25 Oct 2020 17:16:07
User entered '25 Oct 2020 13:16'	System	25 Oct 2020 17:16:07

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 6'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:17', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'None (0)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:22', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'None (0)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:27', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'None (0)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'None (0)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:36', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'None (0)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'None (0)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:43', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcbb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered 'No (N)'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-26T16:07:47', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '676ffcb-456e-420f-bb32-48df26aea730'	System	26 Oct 2020 20:07:50
User entered '26 Oct 2020 16:07'	System	26 Oct 2020 20:07:50

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	21 Oct 2020 22:12:01
User entered 'Day 7'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:04', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'None (0)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:08', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'None (0)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'None (0)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:18', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'None (0)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:22', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'None (0)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:26', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'None (0)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered 'No (N)'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-10-27T16:32:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '7215f7b5-3e2e-4bb0-a86a-b50d2aca8d84'	System	27 Oct 2020 20:32:57
User entered '27 Oct 2020 16:32'	System	27 Oct 2020 20:32:57

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 22:12:01

US3402448

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 22:12:01

US3402448

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	29 Oct 2020 12:45:50

US3402448

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered '28 Oct 2020'	(b) (4) Tammy Kohn (b) (4)	29 Oct 2020 12:45:50
	(b) (4)	

US3402448

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	29 Oct 2020 12:45:50

US3402448

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered empty.	Tammy Kohn (b) (4)	29 Oct 2020 12:45:50

US3402448

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	29 Oct 2020 12:45:54

US3402448

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'I'	System	29 Oct 2020 12:45:54

US3402448

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	04 Nov 2020 16:32:56

US3402448

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered '4 Nov 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Nov 2020 16:32:56

US3402448

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	04 Nov 2020 16:32:56

US3402448

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered empty.	Traci Hull (b) (4)	04 Nov 2020 16:32:56

US3402448

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	04 Nov 2020 16:33:02

US3402448

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'I'	System	04 Nov 2020 16:33:02

US3402448

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:18:22

US3402448

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:18:22

US3402448

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:18:22

US3402448

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	16 Nov 2020 19:18:48
Please review and reconcile.' (Site from System).		
User entered 'Could not reach subject.' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Nov 2020 19:18:48
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	16 Nov 2020 19:18:22
Please review and reconcile.' (Site from System).		
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 19:18:22

US3402448

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:18:54

US3402448

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'I'	System	16 Nov 2020 19:18:54

US3402448

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	16 Nov 2020 19:48:56

US3402448

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '16 Nov 2020'	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 19:48:56
	(b) (4)	

US3402448

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	16 Nov 2020 19:48:56

US3402448

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'VISIT2'	System	16 Nov 2020 19:48:56

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '16 Nov 2020'	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '13:03'	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 20:12:44
	(b) (4)	

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered '16 Nov 2020 13:03'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '36.4' C	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 20:12:44
	(b) (4)	

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '79'	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 20:12:44
	(b) (4)	

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'bpm'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '14'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'breaths/min'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '127'	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 20:12:44
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'mmHg'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '84'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'mmHg'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:12:44

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '16 Nov 2020'	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 20:12:44
	(b) (4)	

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '14:11'	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 20:12:44
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered '16 Nov 2020 14:11'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '36.7' C	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 20:12:44
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Oral (Oral)'	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 20:12:44
	(b) (4)	

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered empty.	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	16 Nov 2020 20:13:03
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Nov 2020 20:13:03
User entered '64' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Nov 2020 20:13:03
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	16 Nov 2020 20:12:44
User entered '6'	System	16 Nov 2020 20:12:44
	Traci Hull (b) (4)	16 Nov 2020 20:12:44
	(b) (4)	

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'bpm'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '14'	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'breaths/min'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '119'	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'mmHg'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '87'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'mmHg'	System	16 Nov 2020 20:12:44

US3402448

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	(b) (4)	16 Nov 2020 20:13:38
	Traci Hull (b) (4)	
	(b) (4)	

US3402448

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '16 Nov 2020'	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 20:13:38
	(b) (4)	

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

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)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'MRNA-1273 OR PLACEBO'	System	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '13:35'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered '16 Nov 2020 13:35'	System	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'ONCE'	System	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'INTRAMUSCULAR'	System	16 Nov 2020 19:19:29

US3402448

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:14:13

US3402448

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '16 Nov 2020'	Traci Hull (b) (4)	16 Nov 2020 20:14:13

US3402448

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '13:23'	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:14:13

US3402448

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered '16 Nov 2020 13:23'	System	16 Nov 2020 20:14:13

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:24:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '16 Nov 2020'	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 20:14:26
	(b) (4)	

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '13:26'	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 20:14:26
	(b) (4)	

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered '16 Nov 2020 13:26'	System	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	16 Nov 2020 20:14:26
	(b) (4)	

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered empty.	System	16 Nov 2020 20:14:26

US3402448

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:14:31

US3402448

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'I'	System	16 Nov 2020 20:14:31

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:20:53', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '188e71a6-903d-47ba-992e-30d26b6fca6b'	System	16 Nov 2020 19:21:25
User entered 'Yes (Y)'	System	16 Nov 2020 19:21:25

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:21:04', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '188e71a6-903d-47ba-992e-30d26b6fca6b' User entered '98.0'	System	16 Nov 2020 19:21:25
	System	16 Nov 2020 19:21:25

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:21:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '188e71a6-903d-47ba-992e-30d26b6fca6b'	System	16 Nov 2020 19:21:25
User entered 'No (N)'	System	16 Nov 2020 19:21:25

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:21:20', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '188e71a6-903d-47ba-992e-30d26b6fca6b' User entered '16 Nov 2020 14:21'	System	16 Nov 2020 19:21:25
	System	16 Nov 2020 19:21:25

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '16 Nov 2020 13:55'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '16 Nov 2020 16:25'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:15', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0e8c56a4-507d-4626-ab51-27a0a87565e2'	System	17 Nov 2020 09:51:44
User entered 'Yes (Y)'	System	17 Nov 2020 09:51:44

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:30', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0e8c56a4-507d-4626-ab51-27a0a87565e2'	System	17 Nov 2020 09:51:44
User entered '98.0'	System	17 Nov 2020 09:51:44

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0e8c56a4-507d-4626-ab51-27a0a87565e2'	System	17 Nov 2020 09:51:44
User entered 'No (N)'	System	17 Nov 2020 09:51:44

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:40', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0e8c56a4-507d-4626-ab51-27a0a87565e2'	System	17 Nov 2020 09:51:44
User entered '17 Nov 2020 04:51'	System	17 Nov 2020 09:51:44

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '16 Nov 2020 17:20'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 2'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:15:41', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '13b5452b-2fb9-40c8-a20d-4c4c4d139ceb'	System	17 Nov 2020 20:16:12
User entered 'Yes (Y)'	System	17 Nov 2020 20:16:12

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:15:54', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '13b5452b-2fb9-40c8-a20d-4c4c4d139ceb'	System	17 Nov 2020 20:16:12
User entered '98.4'	System	17 Nov 2020 20:16:12

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:15:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '13b5452b-2fb9-40c8-a20d-4c4c4d139ceb'	System	17 Nov 2020 20:16:12
User entered 'No (N)'	System	17 Nov 2020 20:16:12

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:16:09', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '13b5452b-2fb9-40c8-a20d-4c4c4d139ceb'	System	17 Nov 2020 20:16:12
User entered '17 Nov 2020 15:16'	System	17 Nov 2020 20:16:12

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 3'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:42:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0962b1ff-d856-410f-ba5b-e611fb486dfb'	System	18 Nov 2020 21:43:23
User entered 'Yes (Y)'	System	18 Nov 2020 21:43:23

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:42:55', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0962b1ff-d856-410f-ba5b-e611fb486dfb' User entered '99.2'	System	18 Nov 2020 21:43:23
	System	18 Nov 2020 21:43:23

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:43:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0962b1ff-d856-410f-ba5b-e611fb486dfb'	System	18 Nov 2020 21:43:23
User entered 'No (N)'	System	18 Nov 2020 21:43:23

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:43:20', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0962b1ff-d856-410f-ba5b-e611fb486dfb'	System	18 Nov 2020 21:43:23
User entered '18 Nov 2020 16:43'	System	18 Nov 2020 21:43:23

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 4'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:08', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd1997dcb-d92a-4e37-a267-cb65d902f912'	System	19 Nov 2020 21:13:41
User entered 'Yes (Y)'	System	19 Nov 2020 21:13:41

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:16', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd1997dcb-d92a-4e37-a267-cb65d902f912'	System	19 Nov 2020 21:13:41
User entered '98.7'	System	19 Nov 2020 21:13:41

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:21', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd1997dcb-d92a-4e37-a267-cb65d902f912'	System	19 Nov 2020 21:13:41
User entered 'No (N)'	System	19 Nov 2020 21:13:41

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:34', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd1997dcb-d92a-4e37-a267-cb65d902f912'	System	19 Nov 2020 21:13:41
User entered '19 Nov 2020 16:13'	System	19 Nov 2020 21:13:41

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 5'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:17:46', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'b19f6219-9fc0-4ccd-92b9-f7e207cdd382'	System	20 Nov 2020 22:18:40
User entered 'Yes (Y)'	System	20 Nov 2020 22:18:40

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:18:20', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'b19f6219-9fc0-4ccd-92b9-f7e207cdd382'	System	20 Nov 2020 22:18:40
User entered '98.2'	System	20 Nov 2020 22:18:40

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:18:29', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'b19f6219-9fc0-4ccd-92b9-f7e207cdd382'	System	20 Nov 2020 22:18:40
User entered 'No (N)'	System	20 Nov 2020 22:18:40

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:18:38', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'b19f6219-9fc0-4ccd-92b9-f7e207cdd382'	System	20 Nov 2020 22:18:40
User entered '20 Nov 2020 17:18'	System	20 Nov 2020 22:18:40

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 6'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:03:28', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '90b6d767-0d33-43cc-b1a7-677126d292fe'	System	21 Nov 2020 17:03:57
User entered 'Yes (Y)'	System	21 Nov 2020 17:03:57

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:03:43', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '90b6d767-0d33-43cc-b1a7-677126d292fe' User entered '98.8'	System	21 Nov 2020 17:03:57
	System	21 Nov 2020 17:03:57

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:03:49', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '90b6d767-0d33-43cc-b1a7-677126d292fe'	System	21 Nov 2020 17:03:57
User entered 'No (N)'	System	21 Nov 2020 17:03:57

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:03:53', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '90b6d767-0d33-43cc-b1a7-677126d292fe' User entered '21 Nov 2020 12:03'	System	21 Nov 2020 17:03:57
	System	21 Nov 2020 17:03:57

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 7'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:56:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4e591ada-ecb3-4810-9cc8-65845face6af'	System	23 Nov 2020 13:56:42
User entered 'Yes (Y)'	System	23 Nov 2020 13:56:42

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:56:29', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4e591ada-ecb3-4810-9cc8-65845face6af' User entered '98.7'	System	23 Nov 2020 13:56:42
	System	23 Nov 2020 13:56:42

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:56:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4e591ada-ecb3-4810-9cc8-65845face6af'	System	23 Nov 2020 13:56:42
User entered 'No (N)'	System	23 Nov 2020 13:56:42

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:56:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4e591ada-ecb3-4810-9cc8-65845face6af' User entered '23 Nov 2020 08:56'	System	23 Nov 2020 13:56:42
	System	23 Nov 2020 13:56:42

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:21:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '5cb9312e-4d63-487c-9077-3f21d93ae309'	System	16 Nov 2020 19:22:25
User entered 'None (1)'	System	16 Nov 2020 19:22:25

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:21:54', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '5cb9312e-4d63-487c-9077-3f21d93ae309'	System	16 Nov 2020 19:22:25
User entered 'No (N)'	System	16 Nov 2020 19:22:25

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:03', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '5cb9312e-4d63-487c-9077-3f21d93ae309'	System	16 Nov 2020 19:22:25
User entered 'No (N)'	System	16 Nov 2020 19:22:25

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '5cb9312e-4d63-487c-9077-3f21d93ae309'	System	16 Nov 2020 19:22:25
User entered 'None (1)'	System	16 Nov 2020 19:22:25

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:21', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '5cb9312e-4d63-487c-9077-3f21d93ae309' User entered '16 Nov 2020 14:22'	System	16 Nov 2020 19:22:25
	System	16 Nov 2020 19:22:25

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '16 Nov 2020 13:55'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '16 Nov 2020 16:25'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:46', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bc79eb27-e1ed-4fc5-8495-09804d5f237f'	System	17 Nov 2020 09:52:13
User entered 'None (1)'	System	17 Nov 2020 09:52:13

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bc79eb27-e1ed-4fc5-8495-09804d5f237f'	System	17 Nov 2020 09:52:13
User entered 'No (N)'	System	17 Nov 2020 09:52:13

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:51:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bc79eb27-e1ed-4fc5-8495-09804d5f237f'	System	17 Nov 2020 09:52:13
User entered 'No (N)'	System	17 Nov 2020 09:52:13

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:03', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bc79eb27-e1ed-4fc5-8495-09804d5f237f'	System	17 Nov 2020 09:52:13
User entered 'None (1)'	System	17 Nov 2020 09:52:13

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:10', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bc79eb27-e1ed-4fc5-8495-09804d5f237f' User entered '17 Nov 2020 04:52'	System	17 Nov 2020 09:52:13
	System	17 Nov 2020 09:52:13

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '16 Nov 2020 17:20'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 2'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:16:16', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4ad0cdc0-7f3a-4fee-9e83-186caa83b790'	System	17 Nov 2020 20:16:52
User entered 'None (1)'	System	17 Nov 2020 20:16:52

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:16:22', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4ad0cdc0-7f3a-4fee-9e83-186caa83b790'	System	17 Nov 2020 20:16:52
User entered 'No (N)'	System	17 Nov 2020 20:16:52

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:16:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4ad0cdc0-7f3a-4fee-9e83-186caa83b790'	System	17 Nov 2020 20:16:52
User entered 'No (N)'	System	17 Nov 2020 20:16:52

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:16:41', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4ad0cdc0-7f3a-4fee-9e83-186caa83b790'	System	17 Nov 2020 20:16:52
User entered 'None (1)'	System	17 Nov 2020 20:16:52

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:16:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '4ad0cdc0-7f3a-4fee-9e83-186caa83b790'	System	17 Nov 2020 20:16:52
User entered '17 Nov 2020 15:16'	System	17 Nov 2020 20:16:52

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 3'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:43:32', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '2f000858-cbd7-471b-94f7-bc4b5a16da58'	System	18 Nov 2020 21:43:57
User entered 'None (1)'	System	18 Nov 2020 21:43:57

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:43:37', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '2f000858-cbd7-471b-94f7-bc4b5a16da58'	System	18 Nov 2020 21:43:57
User entered 'No (N)'	System	18 Nov 2020 21:43:57

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:43:41', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '2f000858-cbd7-471b-94f7-bc4b5a16da58'	System	18 Nov 2020 21:43:57
User entered 'No (N)'	System	18 Nov 2020 21:43:57

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:43:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '2f000858-cbd7-471b-94f7-bc4b5a16da58'	System	18 Nov 2020 21:43:57
User entered 'None (1)'	System	18 Nov 2020 21:43:57

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:43:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '2f000858-cbd7-471b-94f7-bc4b5a16da58'	System	18 Nov 2020 21:43:57
User entered '18 Nov 2020 16:43'	System	18 Nov 2020 21:43:57

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 4'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:43', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3b9c4f88-d4fe-4848-861c-fe3d07d3ce89'	System	19 Nov 2020 21:14:19
User entered 'None (1)'	System	19 Nov 2020 21:14:19

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3b9c4f88-d4fe-4848-861c-fe3d07d3ce89'	System	19 Nov 2020 21:14:19
User entered 'No (N)'	System	19 Nov 2020 21:14:19

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:13:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3b9c4f88-d4fe-4848-861c-fe3d07d3ce89'	System	19 Nov 2020 21:14:19
User entered 'No (N)'	System	19 Nov 2020 21:14:19

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:01', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3b9c4f88-d4fe-4848-861c-fe3d07d3ce89'	System	19 Nov 2020 21:14:19
User entered 'None (1)'	System	19 Nov 2020 21:14:19

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:09', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '3b9c4f88-d4fe-4848-861c-fe3d07d3ce89'	System	19 Nov 2020 21:14:19
User entered '19 Nov 2020 16:14'	System	19 Nov 2020 21:14:19

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 5'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:18:45', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '33660401-c153-4678-afab-849747a1d5be'	System	20 Nov 2020 22:19:14
User entered 'None (1)'	System	20 Nov 2020 22:19:14

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:18:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '33660401-c153-4678-afab-849747a1d5be'	System	20 Nov 2020 22:19:14
User entered 'No (N)'	System	20 Nov 2020 22:19:14

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '33660401-c153-4678-afab-849747a1d5be'	System	20 Nov 2020 22:19:14
User entered 'No (N)'	System	20 Nov 2020 22:19:14

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:03', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '33660401-c153-4678-afab-849747a1d5be'	System	20 Nov 2020 22:19:14
User entered 'None (1)'	System	20 Nov 2020 22:19:14

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:09', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '33660401-c153-4678-afab-849747a1d5be'	System	20 Nov 2020 22:19:14
User entered '20 Nov 2020 17:19'	System	20 Nov 2020 22:19:14

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 6'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:15', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6c9d1dc4-bc67-4936-85c8-7e3b7b671dfb'	System	21 Nov 2020 17:04:37
User entered 'None (1)'	System	21 Nov 2020 17:04:37

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:20', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6c9d1dc4-bc67-4936-85c8-7e3b7b671dfb'	System	21 Nov 2020 17:04:37
User entered 'No (N)'	System	21 Nov 2020 17:04:37

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:24', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6c9d1dc4-bc67-4936-85c8-7e3b7b671dfb'	System	21 Nov 2020 17:04:37
User entered 'No (N)'	System	21 Nov 2020 17:04:37

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:28', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6c9d1dc4-bc67-4936-85c8-7e3b7b671dfb'	System	21 Nov 2020 17:04:37
User entered 'None (1)'	System	21 Nov 2020 17:04:37

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:32', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6c9d1dc4-bc67-4936-85c8-7e3b7b671dfb'	System	21 Nov 2020 17:04:37
User entered '21 Nov 2020 12:04'	System	21 Nov 2020 17:04:37

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 7'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:56:47', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e5dbe9c8-c192-42b1-a051-eb0051b3d82f'	System	23 Nov 2020 13:57:28
User entered 'None (1)'	System	23 Nov 2020 13:57:28

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e5dbe9c8-c192-42b1-a051-eb0051b3d82f'	System	23 Nov 2020 13:57:28
User entered 'No (N)'	System	23 Nov 2020 13:57:28

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:16', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e5dbe9c8-c192-42b1-a051-eb0051b3d82f'	System	23 Nov 2020 13:57:28
User entered 'No (N)'	System	23 Nov 2020 13:57:28

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e5dbe9c8-c192-42b1-a051-eb0051b3d82f'	System	23 Nov 2020 13:57:28
User entered 'None (1)'	System	23 Nov 2020 13:57:28

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:24', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e5dbe9c8-c192-42b1-a051-eb0051b3d82f' User entered '23 Nov 2020 08:57'	System	23 Nov 2020 13:57:28
	System	23 Nov 2020 13:57:28

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:30', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'None (0)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:34', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'None (0)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:37', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'None (0)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:40', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'None (0)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:43', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'None (0)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:46', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'None (0)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f'	System	16 Nov 2020 19:22:58
User entered 'No (N)'	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-16T14:22:55', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8cace60c-7dd3-49b7-9cc6-9cad16953b5f' User entered '16 Nov 2020 14:22'	System	16 Nov 2020 19:22:58
	System	16 Nov 2020 19:22:58

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '16 Nov 2020 13:55'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '16 Nov 2020 16:25'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'None (0)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'None (0)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'None (0)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:54', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'None (0)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:52:57', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'None (0)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:53:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'None (0)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:53:05', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered 'No (N)'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T04:53:09', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'bd139641-3ef0-4ee2-8763-44eeeb507373'	System	17 Nov 2020 09:53:14
User entered '17 Nov 2020 04:53'	System	17 Nov 2020 09:53:14

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '16 Nov 2020 17:20'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 2'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:16:55', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'None (0)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:03', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'None (0)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:08', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'None (0)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'None (0)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:15', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'None (0)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'None (0)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:24', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered 'No (N)'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-17T15:17:37', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a0b20f8d-b682-415c-8f89-1f66cc2f7586'	System	17 Nov 2020 20:17:43
User entered '17 Nov 2020 15:17'	System	17 Nov 2020 20:17:43

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 3'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:01', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'None (0)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:05', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'None (0)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:09', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'None (0)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:14', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'None (0)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:18', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'None (0)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:22', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'None (0)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:32', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered 'No (N)'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-18T16:44:37', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1a5c2a3b-e044-4f73-97b9-f738bab0cd5a'	System	18 Nov 2020 21:44:42
User entered '18 Nov 2020 16:44'	System	18 Nov 2020 21:44:42

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 4'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'None (0)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:34', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'None (0)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'None (0)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'None (0)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:48', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'None (0)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:52', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'None (0)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:14:57', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered 'No (N)'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45159e7f9db483f7)', Time: '2020-11-19T16:15:02', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a956fece-3c6c-4cef-9da7-b739b3a5ca39'	System	19 Nov 2020 21:15:09
User entered '19 Nov 2020 16:15'	System	19 Nov 2020 21:15:09

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 5'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:18', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'None (0)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'None (0)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:38', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'None (0)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:42', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'None (0)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:45', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'None (0)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:19:49', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'None (0)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:20:24', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered 'No (N)'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-20T17:20:29', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ee8e336f-c342-498e-8824-ca23b32afccb'	System	20 Nov 2020 22:20:35
User entered '20 Nov 2020 17:20'	System	20 Nov 2020 22:20:35

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 6'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:38', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'None (0)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:41', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'None (0)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:44', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'None (0)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:47', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'None (0)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'None (0)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:04:53', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'None (0)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:05:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7'	System	21 Nov 2020 17:05:11
User entered 'No (N)'	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-21T12:05:07', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'afd1da54-4141-4dfb-9d1a-dac93a7a60c7' User entered '21 Nov 2020 12:05'	System	21 Nov 2020 17:05:11
	System	21 Nov 2020 17:05:11

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
Data entry locked.	System	16 Nov 2020 19:19:29
User entered 'Day 7'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:29', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'None (0)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'None (0)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:36', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'None (0)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:39', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'None (0)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:42', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'None (0)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:45', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'None (0)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

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)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:57:52', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered 'No (N)'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-11-23T08:58:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '9c676010-bf93-4df2-b116-6de3e91d8953'	System	23 Nov 2020 13:58:05
User entered '23 Nov 2020 08:58'	System	23 Nov 2020 13:58:05

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 19:19:29

US3402448

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:54:38
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 19:19:29

US3402448

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	30 Nov 2020 21:14:14

US3402448

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered '23 Nov 2020'	Traci Hull (b) (4)	30 Nov 2020 21:14:14

US3402448

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4) (b) (4)	30 Nov 2020 21:14:14

US3402448

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered empty.	Traci Hull (b) (4)	30 Nov 2020 21:14:14

US3402448

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	Traci Hull (b) (4)	30 Nov 2020 21:14:03

US3402448

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'I'	System	30 Nov 2020 21:14:03

US3402448

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	30 Nov 2020 21:14:29

US3402448

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered '30 Nov 2020'	Traci Hull (b) (4)	30 Nov 2020 21:14:29

US3402448

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4) (b) (4)	30 Nov 2020 21:14:29

US3402448

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered empty.	Traci Hull (b) (4)	30 Nov 2020 21:14:29

US3402448

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	Traci Hull (b) (4)	30 Nov 2020 21:14:32

US3402448

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'I'	System	30 Nov 2020 21:14:32

US3402448

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	(b) (4)	07 Dec 2020 16:24:12
	Traci Hull (b) (4)	
	(b) (4)	

US3402448

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered '7 Dec 2020'	Traci Hull (b) (4)	07 Dec 2020 16:24:12

US3402448

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4) (b) (4)	07 Dec 2020 16:24:12

US3402448

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	07 Dec 2020 16:24:12
	(b) (4)	

US3402448

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:02
User entered 'Yes (Y)'	Traci Hull (b) (4)	07 Dec 2020 16:24:16

US3402448

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'I'	System	07 Dec 2020 16:24:16

US3402448

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	(b) (4)	
	Jennifer Molstead (b) (4)	11 Dec 2020 19:01:07
	(b) (4)	

US3402448

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '11 Dec 2020'	(b) (4)	
	Jennifer Molstead (b) (4)	11 Dec 2020 19:01:07
	(b) (4)	

US3402448

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	11 Dec 2020 19:01:07

US3402448

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'VISIT3'	System	11 Dec 2020 19:01:07

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '11 Dec 2020'	Jennifer Molstead (b) (4)	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '13:18'	Jennifer Molstead (b) (4)	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered '11 Dec 2020 13:18'	System	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '36.7' C	Jennifer Molstead (b) (4)	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Oral (Oral)'	Jennifer Molstead (b) (4)	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered empty.	Jennifer Molstead (b) (4)	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '75'	Jennifer Molstead (b) (4)	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'bpm'	System	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '15'	Jennifer Molstead (b) (4)	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'breaths/min'	System	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '111'	Jennifer Molstead (b) (4)	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'mmHg'	System	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '77'	Jennifer Molstead (b) (4)	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'mmHg'	System	11 Dec 2020 19:06:41

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57

US3402448

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57

US3402448

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'No (N)'	(b) (4)	Jennifer Molstead (b) (4) 11 Dec 2020 19:06:50
	(b) (4)	

US3402448

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered empty.	Jennifer Molstead (b) (4)	11 Dec 2020 19:06:50

US3402448

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	11 Dec 2020 19:07:08

US3402448

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '11 Dec 2020'	(b) (4)	
	Jennifer Molstead (b) (4)	11 Dec 2020 19:07:08
	(b) (4)	

US3402448

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered '13:23'	Jennifer Molstead (b) (4)	11 Dec 2020 19:07:08

US3402448

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered '11 Dec 2020 13:23'	System	11 Dec 2020 19:07:08

US3402448

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:33:55
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	11 Dec 2020 19:07:13

US3402448

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'I'	System	11 Dec 2020 19:07:13

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2020-12-18T01:48:02', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8b228817-e433-4583-9cf2-ccf30106729f'	System	18 Dec 2020 06:48:26
User entered 'No (N)'	System	18 Dec 2020 06:48:26

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2020-12-18T01:48:11', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8b228817-e433-4583-9cf2-ccf30106729f'	System	18 Dec 2020 06:48:26
User entered 'No (N)'	System	18 Dec 2020 06:48:26

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-12-18T01:48:22', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '8b228817-e433-4583-9cf2-ccf30106729f' User entered '18 Dec 2020 01:48:22'	System	18 Dec 2020 06:48:26
	System	18 Dec 2020 06:48:26

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2020-12-25T08:26:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'b3383aa0-9080-4d50-8cd2-5dcc282e9c47'	System	25 Dec 2020 13:26:33
User entered 'No (N)'	System	25 Dec 2020 13:26:33

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2020-12-25T08:26:13', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'b3383aa0-9080-4d50-8cd2-5dcc282e9c47'	System	25 Dec 2020 13:26:33
User entered 'No (N)'	System	25 Dec 2020 13:26:33

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2020-12-25T08:26:28', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'b3383aa0-9080-4d50-8cd2-5dcc282e9c47'	System	25 Dec 2020 13:26:33
User entered '25 Dec 2020 08:26:28'	System	25 Dec 2020 13:26:33

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-01-01T00:47:31', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e1b6318f-4811-49c4-80e3-b6cbf2cf8d90'	System	01 Jan 2021 05:47:54
User entered 'No (N)'	System	01 Jan 2021 05:47:54

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-01-01T00:47:35', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e1b6318f-4811-49c4-80e3-b6cbf2cf8d90'	System	01 Jan 2021 05:47:54
User entered 'No (N)'	System	01 Jan 2021 05:47:54

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-01-01T00:47:51', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e1b6318f-4811-49c4-80e3-b6cbf2cf8d90'	System	01 Jan 2021 05:47:54
User entered '01 Jan 2021 00:47:51'	System	01 Jan 2021 05:47:54

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-01-08T12:46:08', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'f1833562-7522-4431-ba9c-0070312e49ef'	System	08 Jan 2021 17:46:32
User entered 'No (N)'	System	08 Jan 2021 17:46:32

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-01-08T12:46:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'f1833562-7522-4431-ba9c-0070312e49ef'	System	08 Jan 2021 17:46:32
User entered 'No (N)'	System	08 Jan 2021 17:46:32

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-01-08T12:46:27', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'f1833562-7522-4431-ba9c-0070312e49ef' User entered '08 Jan 2021 12:46:27'	System	08 Jan 2021 17:46:32
	System	08 Jan 2021 17:46:32

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-01-15T19:14:18', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0541858f-7c76-4f07-9bcb-c94ef5820b30'	System	16 Jan 2021 00:14:44
User entered 'No (N)'	System	16 Jan 2021 00:14:44

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-01-15T19:14:23', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0541858f-7c76-4f07-9bcb-c94ef5820b30'	System	16 Jan 2021 00:14:44
User entered 'No (N)'	System	16 Jan 2021 00:14:44

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-01-15T19:14:40', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '0541858f-7c76-4f07-9bcb-c94ef5820b30'	System	16 Jan 2021 00:14:44
User entered '15 Jan 2021 19:14:40'	System	16 Jan 2021 00:14:44

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-01-22T17:02:43', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'f6736d52-da55-4033-8921-c8843ce50de3'	System	22 Jan 2021 22:03:03
User entered 'No (N)'	System	22 Jan 2021 22:03:03

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-01-22T17:02:50', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'f6736d52-da55-4033-8921-c8843ce50de3'	System	22 Jan 2021 22:03:03
User entered 'No (N)'	System	22 Jan 2021 22:03:03

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-01-22T17:02:58', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'f6736d52-da55-4033-8921-c8843ce50de3' User entered '22 Jan 2021 17:02:58'	System	22 Jan 2021 22:03:03
	System	22 Jan 2021 22:03:03

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-01-29T14:46:07', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6b911660-353c-4e0e-a577-c6138455ee58'	System	29 Jan 2021 19:46:31
User entered 'No (N)'	System	29 Jan 2021 19:46:31

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-01-29T14:46:16', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6b911660-353c-4e0e-a577-c6138455ee58'	System	29 Jan 2021 19:46:31
User entered 'No (N)'	System	29 Jan 2021 19:46:31

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-01-29T14:46:27', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '6b911660-353c-4e0e-a577-c6138455ee58' User entered '29 Jan 2021 14:46:27'	System	29 Jan 2021 19:46:31

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-02-05T18:39:08', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a03944f6-8e90-404c-bbda-1701644c2af2'	System	05 Feb 2021 23:39:30
User entered 'No (N)'	System	05 Feb 2021 23:39:30

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-02-05T18:39:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a03944f6-8e90-404c-bbda-1701644c2af2'	System	05 Feb 2021 23:39:30
User entered 'No (N)'	System	05 Feb 2021 23:39:30

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-02-05T18:39:25', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a03944f6-8e90-404c-bbda-1701644c2af2'	System	05 Feb 2021 23:39:30
User entered '05 Feb 2021 18:39:25'	System	05 Feb 2021 23:39:30

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-02-12T16:51:14', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ef65abb4-0959-4dd1-81ce-2938af02615b'	System	12 Feb 2021 21:51:38
User entered 'No (N)'	System	12 Feb 2021 21:51:38

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-02-12T16:51:19', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ef65abb4-0959-4dd1-81ce-2938af02615b'	System	12 Feb 2021 21:51:38
User entered 'No (N)'	System	12 Feb 2021 21:51:38

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-02-12T16:51:31', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'ef65abb4-0959-4dd1-81ce-2938af02615b'	System	12 Feb 2021 21:51:38
User entered '12 Feb 2021 16:51:31'	System	12 Feb 2021 21:51:38

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-02-19T02:45:40', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd07ec076-53d5-4243-9842-752d168f7325'	System	19 Feb 2021 07:46:00
User entered 'No (N)'	System	19 Feb 2021 07:46:00

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-02-19T02:45:45', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd07ec076-53d5-4243-9842-752d168f7325'	System	19 Feb 2021 07:46:00
User entered 'No (N)'	System	19 Feb 2021 07:46:00

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-02-19T02:45:55', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'd07ec076-53d5-4243-9842-752d168f7325'	System	19 Feb 2021 07:46:00
User entered '19 Feb 2021 02:45:55'	System	19 Feb 2021 07:46:00

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-02-26T00:25:38', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1e1f168a-c466-4ca7-9fb2-a009d77bd214'	System	26 Feb 2021 05:26:03
User entered 'No (N)'	System	26 Feb 2021 05:26:03

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-02-26T00:25:47', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1e1f168a-c466-4ca7-9fb2-a009d77bd214'	System	26 Feb 2021 05:26:03
User entered 'No (N)'	System	26 Feb 2021 05:26:03

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-02-26T00:25:59', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1e1f168a-c466-4ca7-9fb2-a009d77bd214' User entered '26 Feb 2021 00:25:59'	System	26 Feb 2021 05:26:03

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-03-05T10:56:33', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a5ec3bae-3e78-41ed-afad-b807074c649d'	System	05 Mar 2021 17:57:20
User entered 'No (N)'	System	05 Mar 2021 17:57:20

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-03-05T10:56:38', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a5ec3bae-3e78-41ed-afad-b807074c649d'	System	05 Mar 2021 17:57:20
User entered 'No (N)'	System	05 Mar 2021 17:57:20

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-03-05T10:56:53', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'a5ec3bae-3e78-41ed-afad-b807074c649d'	System	05 Mar 2021 17:57:20
User entered '05 Mar 2021 10:56:53'	System	05 Mar 2021 17:57:20

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-03-12T11:41:56-07:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '270e9ee4-aa3f-4fe9-9a68-7e9e07861af7'	System	12 Mar 2021 18:42:12
User entered 'No (N)'	System	12 Mar 2021 18:42:12

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-03-12T11:42:02-07:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '270e9ee4-aa3f-4fe9-9a68-7e9e07861af7'	System	12 Mar 2021 18:42:12
User entered 'No (N)'	System	12 Mar 2021 18:42:12

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-03-12T11:42:08-07:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '270e9ee4-aa3f-4fe9-9a68-7e9e07861af7' User entered '12 Mar 2021 11:42:08'	System	12 Mar 2021 18:42:12
	System	12 Mar 2021 18:42:12

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-03-29T18:06:53-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1ace7d96-90b4-48a6-87bc-cc7cca36732a' User entered 'Yes (Y)'	System	29 Mar 2021 22:14:29
	System	29 Mar 2021 22:14:29

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-03-29T18:07:06-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1ace7d96-90b4-48a6-87bc-cc7cca36732a'	System	29 Mar 2021 22:14:29
User entered 'No (N)'	System	29 Mar 2021 22:14:29

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-03-29T18:07:11-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1ace7d96-90b4-48a6-87bc-cc7cca36732a'	System	29 Mar 2021 22:14:29
User entered 'No (N)'	System	29 Mar 2021 22:14:29

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-03-29T18:07:19-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1ace7d96-90b4-48a6-87bc-cc7cca36732a'	System	29 Mar 2021 22:14:29
User entered 'Yes (Y)'	System	29 Mar 2021 22:14:29

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Please 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 (f1b8aa5a37a01477)', Time: '2021-03-29T18:07:32-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1ace7d96-90b4-48a6-87bc-cc7cca36732a'	System	29 Mar 2021 22:14:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Mar 2021 22:14:29

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-03-29T18:07:42-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1ace7d96-90b4-48a6-87bc-cc7cca36732a' User entered '29 Mar 2021 18:07:42'	System	29 Mar 2021 22:14:29
	System	29 Mar 2021 22:14:29

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-04-02T19:10:13-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1196c692-214c-4a19-9a72-dc24c15e79d4'	System	02 Apr 2021 23:11:01
User entered 'Yes (Y)'	System	02 Apr 2021 23:11:01

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-04-02T19:10:17-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1196c692-214c-4a19-9a72-dc24c15e79d4'	System	02 Apr 2021 23:11:01
User entered 'No (N)'	System	02 Apr 2021 23:11:01

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-04-02T19:10:24-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1196c692-214c-4a19-9a72-dc24c15e79d4'	System	02 Apr 2021 23:11:01
User entered 'No (N)'	System	02 Apr 2021 23:11:01

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-04-02T19:10:30-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1196c692-214c-4a19-9a72-dc24c15e79d4'	System	02 Apr 2021 23:11:01
User entered 'Yes (Y)'	System	02 Apr 2021 23:11:01

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Please 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 (f1b8aa5a37a01477)', Time: '2021-04-02T19:10:37-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1196c692-214c-4a19-9a72-dc24c15e79d4'	System	02 Apr 2021 23:11:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Apr 2021 23:11:01

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-04-02T19:10:48-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '1196c692-214c-4a19-9a72-dc24c15e79d4'	System	02 Apr 2021 23:11:01
User entered '02 Apr 2021 19:10:48'	System	02 Apr 2021 23:11:01

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-04-12T00:03:00-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '48a15262-7991-4ff8-823d-4f5121f60884'	System	12 Apr 2021 04:03:47
User entered 'No (N)'	System	12 Apr 2021 04:03:47

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-04-12T00:03:05-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '48a15262-7991-4ff8-823d-4f5121f60884'	System	12 Apr 2021 04:03:47
User entered 'No (N)'	System	12 Apr 2021 04:03:47

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-04-12T00:03:19-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '48a15262-7991-4ff8-823d-4f5121f60884'	System	12 Apr 2021 04:03:47
User entered '12 Apr 2021 00:03:19'	System	12 Apr 2021 04:03:47

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[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 (f1b8aa5a37a01477)', Time: '2021-04-30T23:51:24-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '430f89d3-0e8b-497d-85be-a13bc8c7a627'	System	01 May 2021 04:48:52
User entered 'No (N)'	System	01 May 2021 04:48:52

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

Have you been exposed to someone with 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 (f1b8aa5a37a01477)', Time: '2021-04-30T23:51:29-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '430f89d3-0e8b-497d-85be-a13bc8c7a627'	System	01 May 2021 04:48:52
User entered 'No (N)'	System	01 May 2021 04:48:52

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-04-30T23:51:48-04:00', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: '430f89d3-0e8b-497d-85be-a13bc8c7a627'	System	01 May 2021 04:48:52
User entered '30 Apr 2021 23:51:48'	System	01 May 2021 04:48:52

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '16 Dec 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '20 Dec 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '23 Dec 2022 00:01'	System	20 Nov 2020 13:26:07

US3402448

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:26:07
Amendment Manager: User entered '27 Dec 2022 23:59'	System	20 Nov 2020 13:26:07

US3402448

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:24:13

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-03-05T10:57:12', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e92feb28-3431-4c53-acd5-342923a7324e'	System	05 Mar 2021 17:57:20
User entered 'No (N)'	System	05 Mar 2021 17:57:20

US3402448

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:24:13

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:17:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8aa5a37a01477)', Time: '2021-03-05T10:57:17', User OID: 'PatientReportedOutcome (US3402448)', ODM File OID: 'e92feb28-3431-4c53-acd5-342923a7324e'	System	05 Mar 2021 17:57:20
User entered '05 Mar 2021 10:57:17'	System	05 Mar 2021 17:57:20

US3402448

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:35:25
User entered 'Yes (Y)'	(b) (4)	12 Feb 2021 14:52:28
	Traci Hull (b) (4)	
	(b) (4)	

US3402448

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:35:25
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:19:23
User entered '8 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	12 Feb 2021 14:56:32
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as is' (Site from System).	Traci Hull (b) (4) (b) (4)	12 Feb 2021 14:54:08
User entered '09 Nov 2020' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	12 Feb 2021 14:53:16
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Feb 2021 14:52:28
User entered '9 Nov 2020'	Traci Hull (b) (4) (b) (4)	12 Feb 2021 14:52:28

US3402448

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:35:25
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	12 Feb 2021 14:52:28

US3402448

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:35:25
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	12 Feb 2021 14:52:28
	(b) (4)	

US3402448

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:35:25
User entered 'Yes (Y)'	Traci Hull (b) (4)	12 Feb 2021 14:54:14

US3402448

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:06:57
User entered 'I'	System	12 Feb 2021 14:54:14

US3402448

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:57:01
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	12 Feb 2021 14:54:29
	(b) (4)	

US3402448

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:57:01
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '11 Feb 2021'	(b) (4)	
	Traci Hull (b) (4)	12 Feb 2021 14:54:29
	(b) (4)	

US3402448

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:57:01
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	12 Feb 2021 14:54:29

US3402448

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:57:01
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	12 Feb 2021 14:54:29
	(b) (4)	

US3402448

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:57:01
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4)	12 Feb 2021 14:54:34
	Traci Hull (b) (4)	
	(b) (4)	

US3402448

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:57:01
User entered 'I'	System	12 Feb 2021 14:54:34

US3402448

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:57:01
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:58

US3402448

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:57:01
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '15 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:58
	(b) (4)	

US3402448

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:57:01
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:58

US3402448

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:57:01
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:58
	(b) (4)	

US3402448

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:57:01
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:56:01
	(b) (4)	

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Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:57:01
User entered 'I'	System	29 Mar 2021 13:56:01

US3402448

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	13 Apr 2021 15:47:36
	(b) (4)	

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Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
	(b) (4)	
User entered '13 Apr 2021'	Tammy Kohn (b) (4)	13 Apr 2021 15:47:36
	(b) (4)	

US3402448

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	13 Apr 2021 15:47:36
	(b) (4)	

US3402448

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	13 Apr 2021 15:47:36
	(b) (4)	

US3402448

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	13 Apr 2021 15:47:41
	(b) (4)	

US3402448

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 15:47:41

US3402448

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

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:14:53

US3402448

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

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '22 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	22 Jan 2021 15:14:53
	(b) (4)	

US3402448

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

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	22 Jan 2021 15:14:53

US3402448

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

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 15:14:53

US3402448

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:13

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '06 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	22 Jan 2021 15:15:23
	(b) (4)	

US3402448

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:13

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '0'	(b) (4) Traci Hull (b) (4)	08 Apr 2021 13:21:06
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 15:41:55

US3402448

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:13

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:15:23

US3402448

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:13

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
	Traci Hull (b) (4)	08 Apr 2021 13:21:06
Amendment Manager inserted this DataPoint.	(b) (4)	
	System	06 Mar 2021 15:41:55

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:13

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User closed query 'Per IRT, subject was unblinded on 22JAN2021. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:13:27
Query 'Per IRT, subject was unblinded on 22JAN2021. Please review and reconcile. ' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	08 Apr 2021 13:21:23
User entered '22 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	08 Apr 2021 13:21:06
User opened query 'Per IRT, subject was unblinded on 22JAN2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:59:12
User entered '21 Jan 2021'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:15:23

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:13

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:15:23

US3402448

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:13

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:15:23

US3402448

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:13

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:15:23

US3402448

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:13

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:15:23

US3402448

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:13

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'I'	System	22 Jan 2021 15:15:23

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:13

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'I'	System	22 Jan 2021 15:15:23

US3402448

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered empty.	System	22 Jan 2021 15:17:12
DataPoint set to visible.	System	22 Jan 2021 15:15:23

US3402448

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered empty.	System	22 Jan 2021 15:17:12
DataPoint set to visible.	System	22 Jan 2021 15:15:23

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '22 Jan 2021'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '08:56'	Traci Hull (b) (4)	22 Jan 2021 15:17:12

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered '22 Jan 2021 08:56'	System	22 Jan 2021 15:17:12

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '36.6' C	(b) (4)	
	Traci Hull (b) (4)	22 Jan 2021 15:17:12
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '66'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'bpm'	System	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '14'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'breaths/min'	System	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '118'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'mmHg'	System	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '82'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'mmHg'	System	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered empty.	System	22 Jan 2021 15:17:12
DataPoint set to visible.	System	22 Jan 2021 15:15:23

US3402448

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:17:12

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '22 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	22 Jan 2021 15:17:12
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '10:01'	Traci Hull (b) (4)	22 Jan 2021 15:17:12

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered '22 Jan 2021 10:01'	System	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '36.5' C	(b) (4)	
	Traci Hull (b) (4)	22 Jan 2021 15:17:12
	(b) (4)	

US3402448

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12
	(b) (4)	

US3402448

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '61'	(b) (4)	
	Traci Hull (b) (4)	22 Jan 2021 15:17:12
	(b) (4)	

US3402448

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'bpm'	System	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '14'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'breaths/min'	System	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '144'	(b) (4) Traci Hull (b) (4) (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'mmHg'	System	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '83'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:12

US3402448

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'mmHg'	System	22 Jan 2021 15:17:12

US3402448

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4)	22 Jan 2021 15:17:18
	Traci Hull (b) (4)	
	(b) (4)	

US3402448

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '22 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	22 Jan 2021 15:17:18
	(b) (4)	

US3402448

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

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:40

US3402448

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

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:40

US3402448

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

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

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)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:40

US3402448

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

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'mRNA-1273'	System	22 Jan 2021 15:17:40
DataPoint set to visible.	System	22 Jan 2021 15:15:23

US3402448

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

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '22 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	22 Jan 2021 15:17:40
	(b) (4)	

US3402448

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

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '09:30'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:17:40

US3402448

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

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered '22 Jan 2021 09:30'	System	22 Jan 2021 15:17:40

US3402448

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

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4)	22 Jan 2021 15:17:40

US3402448

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

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'ONCE'	System	22 Jan 2021 15:17:40

US3402448

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

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 15:17:40

US3402448

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:15:33

US3402448

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '22 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	22 Jan 2021 15:15:33
	(b) (4)	

US3402448

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '08:35'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:15:33

US3402448

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered '22 Jan 2021 08:35'	System	22 Jan 2021 15:15:33

US3402448

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:15:47

US3402448

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '22 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	22 Jan 2021 15:15:47
	(b) (4)	

US3402448

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:13

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '08:35'	(b) (4)	
	Traci Hull (b) (4)	22 Jan 2021 15:15:47
	(b) (4)	

US3402448

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:13

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered '22 Jan 2021 08:35'	System	22 Jan 2021 15:15:47

US3402448

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

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	22 Jan 2021 15:15:56

US3402448

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

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'I'	System	22 Jan 2021 15:15:56

US3402448

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 19:02:01

US3402448

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '29 Jan 2021'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 19:02:01

US3402448

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 19:02:01

US3402448

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 19:02:01
	(b) (4)	

US3402448

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	01 Feb 2021 19:02:06

US3402448

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'I'	System	01 Feb 2021 19:02:06

US3402448

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'I'	System	01 Feb 2021 19:02:06
DataPoint set to visible.	System	01 Feb 2021 19:02:06

US3402448

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: PPD has 16MAR2021 Immuno sample (sample bar code: 1F638155439) and labelled as OL-3, which is missing in EDC. Please review if immuno sample was collected on 16-MAR-2021 then update the Immunogenicity form under OL-D57. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 09:54:18
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: PPD has 16MAR2021 Immuno sample (sample bar code: 1F638155439) and labelled as OL-3, which is missing in EDC. Please review if immuno sample was collected on 16-MAR-2021 then update the Immunogenicity form under OL-D57. Thank you.' answered with 'OL D57 IS ENTERED AND WAS DONE ON 16 MAR 2021 WHICH IS CORRECT' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 13:30:28
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: PPD has 16MAR2021 Immuno sample (sample bar code: 1F638155439) and labelled as OL-3, which is missing in EDC. Please review if immuno sample was collected on 16-MAR-2021 then update the Immunogenicity form under OL-D57. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 08:16:12
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 21:19:32

US3402448

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '19 Feb 2021' reason for change: New Information	(b) (4)	26 Feb 2021 16:12:22
User entered '23 Feb 2021'	Traci Hull (b) (4)	26 Feb 2021 16:12:22
	(b) (4)	
	Tammy Kohn (b) (4)	23 Feb 2021 21:19:32
	(b) (4)	

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Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Clinic (Clinic)'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:19:32

US3402448

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'OLD29'	System	23 Feb 2021 21:19:32

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Feb 2021 16:12:36
User entered '19 Feb 2021' reason for change: New Information	Traci Hull (b) (4)	26 Feb 2021 16:12:36
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Feb 2021 16:12:22
User entered '23 Feb 2021'	Tammy Kohn (b) (4)	23 Feb 2021 21:21:19
	(b) (4)	

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '08:16'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered '19 Feb 2021 08:16'	System	26 Feb 2021 16:12:36
User entered '23 Feb 2021 08:16'	System	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '97.7' F	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '85'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'bpm'	System	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '18'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'breaths/min'	System	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '134'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'mmHg'	System	23 Feb 2021 21:21:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '85'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'mmHg'	System	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Feb 2021 16:12:36
User entered '19 Feb 2021' reason for change: New Information	Traci Hull (b) (4)	26 Feb 2021 16:12:36
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Feb 2021 16:12:22
User entered '23 Feb 2021'	Tammy Kohn (b) (4)	23 Feb 2021 21:21:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '09:16'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered '19 Feb 2021 09:16'	System	26 Feb 2021 16:12:36
User entered '23 Feb 2021 09:16'	System	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '97.1' F	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '75'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'bpm'	System	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '16'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'breaths/min'	System	23 Feb 2021 21:21:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '148'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'mmHg'	System	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '86'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'mmHg'	System	23 Feb 2021 21:21:19

US3402448

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:31

US3402448

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	26 Feb 2021 16:12:46
User entered '19 Feb 2021' reason for change: New Information	Traci Hull (b) (4)	26 Feb 2021 16:12:46
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	26 Feb 2021 16:12:22
User entered '23 Feb 2021'	Tammy Kohn (b) (4)	23 Feb 2021 21:21:31

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:54

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:54

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

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)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	Tammy Kohn (b) (4)	23 Feb 2021 21:21:54

US3402448

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'mRNA-1273'	System	23 Feb 2021 21:21:54
DataPoint set to visible.	System	01 Feb 2021 19:02:06

US3402448

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	26 Feb 2021 16:12:57
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	26 Feb 2021 16:12:57
User entered '19 Feb 2021' reason for change: New Information	Traci Hull (b) (4)	26 Feb 2021 16:12:57
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	26 Feb 2021 16:12:22
User entered '23 Feb 2021'	System	26 Feb 2021 16:12:22
	Tammy Kohn (b) (4)	23 Feb 2021 21:21:54
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '08:45'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:54

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered '19 Feb 2021 08:45'	System	26 Feb 2021 16:12:57
User entered '23 Feb 2021 08:45'	System	23 Feb 2021 21:21:54

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Left Arm (LEFT ARM)'	Tammy Kohn (b) (4)	23 Feb 2021 21:21:54

US3402448

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'ONCE'	System	23 Feb 2021 21:21:54

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'INTRAMUSCULAR'	System	23 Feb 2021 21:21:54

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:21:58

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'I'	System	23 Feb 2021 21:21:58

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	26 Feb 2021 16:10:59
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
	System	26 Feb 2021 16:12:57
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	26 Feb 2021 16:12:57
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Feb 2021 16:10:59
User entered '26 Feb 2021'	Traci Hull (b) (4)	26 Feb 2021 16:10:59
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	26 Feb 2021 16:10:59

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	26 Feb 2021 16:10:59
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	26 Feb 2021 16:13:18

US3402448

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'I'	System	26 Feb 2021 16:13:18

US3402448

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:54:31

US3402448

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '16 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:54:31

US3402448

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Clinic (Clinic)'	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:54:31

US3402448

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered 'OLD57'	System	29 Mar 2021 13:54:31

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:12

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered empty.	System	29 Mar 2021 13:55:12

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered empty.	System	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered empty.	System	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered empty.	System	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered empty.	System	29 Mar 2021 13:55:12

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07

US3402448

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:13

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07

US3402448

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'No (N)'	(b) (4)	
	Tammy Kohn (b) (4)	29 Mar 2021 13:55:18
	(b) (4)	

US3402448

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered empty.	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:18

US3402448

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:27

US3402448

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '16 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:27
	(b) (4)	

US3402448

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User entered '14:11'	(b) (4) Tammy Kohn (b) (4)	29 Mar 2021 13:55:27

US3402448

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:19:07
User entered '16 Mar 2021 14:11'	System	29 Mar 2021 13:55:27

US3402448

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:24:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:00:19
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 159 (29MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:41:48
Query 'Per DM CLR: Per Safety Follow Up Diary Day 159 (29MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'SUBJECT CONTACTED ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	05 Apr 2021 13:32:37
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 159 (29MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 10:38:17
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:53:27
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:16:15

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:23
User entered	System	17 Nov 2020 13:22:19
'USA-US059-2020-mRNA-1273-P301000017'		
User entered 'New'	(b) (4), (b) (6)	17 Nov 2020 13:22:19

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User closed query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 14:14:03
Query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Subject did have symptoms, but did not call site ' (Site from DM).	Jennifer Molstead (b) (4)	17 Dec 2020 19:16:19
User opened query 'Per MM, please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 15:58:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 18:20:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 18:20:46
Data point term sent to Coder	System	16 Nov 2020 18:19:48
User entered 'WORSENING OF eMPHYSEMA'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '09 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '11 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

Severity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User closed query 'PV Query: Since the subject was hospitalized for the event of worsening of emphysema, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:36:22
Query 'PV Query: Since the subject was hospitalized for the event of worsening of emphysema, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	25 Nov 2020 03:39:39
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	25 Nov 2020 03:39:29
User opened query 'PV Query: Since the subject was hospitalized for the event of worsening of emphysema, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:56:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'I'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '09 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '11 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'None (NONE)'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

None

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'I'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User closed query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:36:28
Query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' answered with 'this would be that she was sent home presently with oxygen' (Site from Safety).	Jennifer Molstead (b) (4)	25 Nov 2020 03:39:02
User opened query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:56:35
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44
	(b) (4)	

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'SUBJECT WAS SENT HOME ON 2 LITERS OF CONTINUOUS OXYGEN'	Jennifer Molstead (b) (4) (b) (4)	16 Nov 2020 18:19:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 21:50:02
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 21:49:56
User opened query '. PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 21:49:48
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
User closed query 'PV Query: Please report if there were any identified triggers for the worsening of the subject's emphysema.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 15:48:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 15:48:17
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 15:48:11
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 15:48:05
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'AWAITING MEDICAL RECORDS' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 13:58:13

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'AWAITING MEDICAL RECORDS' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 13:58:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'AWAITING MEDICAL RECORDS' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 13:58:01
Query 'PV Query: Please report if there were any identified triggers for the worsening of the subject's emphysema.' answered with 'NO IDENTIFIED TRIGGERS FOR THE WORSENING OF EMPHYSEMA' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 13:57:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User opened query 'PV Query: Please report if there were any identified triggers for the worsening of the subject's emphysema.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 21:08:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 21:08:28
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 21:08:24
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 21:08:18
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:51:16

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:51:15
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:51:13
User closed query 'PV Query: Please report if there were any identified triggers for the worsening of the subject's emphysema.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:51:10
Query 'PV Query: Please report if there were any identified triggers for the worsening of the subject's emphysema.' answered with 'NO RECORDS RECIEVED. ' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 21:50:53
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'NO RECORDS RECIEVED. ' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 21:50:48
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'NO RECORDS RECIEVED. ' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 21:50:44
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'NO RECORDS RECIEVED. ' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 21:50:40
Query 'PV Query: Please provide treatment given (in addition to oxygen) for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).'	(b) (4), (b) (6)	01 Dec 2020 18:10:25
canceled (Site from Safety).		

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query:Please report if there were any identified triggers for the worsening of the subject's emphysema.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:56:49
User opened query 'PV Query: Please provide treatment given (in addition to oxygen) for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:56:42
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:56:26
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:56:19
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:55:56
User entered 'AWAITING MEDICAL RECORDS'	Jennifer Molstead (b) (4)	16 Nov 2020 18:19:44

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 18:19:44

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 18:19:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 18:19:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:37:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:37:14
Data point term sent to Coder	System	05 Apr 2021 13:36:24
User entered 'SINUSITIS'	Tammy Kohn (b) (4) (b) (4)	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'No (N)'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'No (N)'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	(b) (4) Tammy Kohn (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '18 Mar 2021'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Apr 2021 13:35:58
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Apr 2021 13:35:58
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Apr 2021 13:35:36
User entered '06:00'	Tammy Kohn (b) (4) (b) (4)	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User entered empty.	System	05 Apr 2021 13:35:58
User entered '18 Mar 2021 06:00'	System	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'No (N)'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '29 Mar 2021'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:00
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	05 Apr 2021 13:35:58
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	05 Apr 2021 13:35:58
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	05 Apr 2021 13:35:36
User entered '09:00'	Tammy Kohn (b) (4) (b) (4)	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4) (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User entered empty.	System	05 Apr 2021 13:35:58
User entered '29 Mar 2021 09:00'	System	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'No (N)'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

US3402448

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'Not Related (NOT RELATED)'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'Not Related (NOT RELATED)'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'None (NONE)'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'l'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered '0'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:00
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 13:35:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User entered '0'	System	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
User entered '1'	System	05 Apr 2021 13:35:36
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:54:50
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	05 Apr 2021 13:34:03
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	05 Mar 2021 20:10:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:24:13

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:16:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 14:57:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 14:57:46
Data point term sent to Coder Coding entries removed.	System Tammy Kohn (b) (4)	08 Apr 2021 14:13:07 08 Apr 2021 14:12:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Oct 2020 05:37:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Oct 2020 05:37:28
Data point term sent to Coder User entered 'CELEBREX'	System Tammy Kohn (b) (4)	21 Oct 2020 23:18:42 21 Oct 2020 23:18:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:18:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User closed query 'Per DM CLR: Please review Indication and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, etc.). Please update and reconcile with MH/AE eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:53:42
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
Query 'Per DM CLR: Please review Indication and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, etc.). Please update and reconcile with MH/AE eCRF so there would be an appropriate match. Otherwise, clarify. ' answered with 'UPDATED PER MEDICATION HISTORY LEFT KNEE OSTEOARTHRITIS' (Site from DM).	(b) (4) Tammy Kohn (b) (4)	08 Apr 2021 14:13:02
User entered 'LEFT KNEE OSTEOARTHRITIS' reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Apr 2021 14:12:52
User opened query 'Per DM CLR: Please review Indication and please update to specify the type of Arthritis (e.g. Osteoarthritis, Rheumatoid, etc.). Please update and reconcile with MH/AE eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 00:02:23
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 23:18:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 23:18:21
User entered 'LEFT KNEE ARTHRITIS' reason for change: Data Entry Error	Tammy Kohn (b) (4)	21 Oct 2020 23:18:21
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 23:18:05
User entered empty.	Tammy Kohn (b) (4)	21 Oct 2020 23:18:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '200'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:18:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'twice daily (BID)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:18:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:18:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:18:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:18:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'UN UNK 2018'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:18:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:18:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 23:18:27
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	21 Oct 2020 23:18:27
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	21 Oct 2020 23:18:05
	Tammy Kohn (b) (4)	21 Oct 2020 23:18:05
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:18:05

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:20:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:20:37
Data point term sent to Coder	System	21 Oct 2020 23:19:42
User entered 'ATORVASTATIN'	Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'HYPERCHOLESTERDEMIA'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '40'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:19:20
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'once daily (QD)'	Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:19:20
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'UN UNK 2006'	Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:19:20

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 04:58:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 04:58:26
Data point term sent to Coder	System	21 Oct 2020 23:20:43
User entered 'TOPIRAMATE'	Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'SCHIZOAFFECTIVE DISORDER'	Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '50'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:20:30
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'twice daily (BID)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'UN UNK 2012'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:20:30

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Oct 2020 05:11:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:11:23
Data point term sent to Coder	System	21 Oct 2020 23:21:47
User entered 'OLANZAPINE'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'SCHIZOAFFECTIVE DISORDER'	Tammy Kohn (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '20'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:21:39
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'once daily (QD)'	Tammy Kohn (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:21:39
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:21:39
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'UN UNK 2016'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:21:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Oct 2020 23:23:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:23:40
Data point term sent to Coder	System	21 Oct 2020 23:22:50
User entered 'OXYBUTININ'	Tammy Kohn (b) (4)	21 Oct 2020 23:22:34
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'OVERACTIVE BLADDER'	Tammy Kohn (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '10'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:22:34
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'once daily (QD)'	Tammy Kohn (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:22:34
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'UN UNK 2012'	Tammy Kohn (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:22:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:24:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	21 Oct 2020 23:24:42
Data point term sent to Coder	System	21 Oct 2020 23:23:51
User entered 'LOSARTAN POTASSIUM'	Tammy Kohn (b) (4)	21 Oct 2020 23:23:26
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'HYPERTENSION'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '100'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'once daily (QD)'	Tammy Kohn (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'UN UNK 2010'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:23:26

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 23:25:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:25:42
Data point term sent to Coder	System	21 Oct 2020 23:24:59
User entered 'SERTRALINE'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'DEPRESSION'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User closed query 'PER DM CLR: RE-QUERY: Per response 'CORRECTED DOSAGE FROM 40 MG TO 50 MG. However, dose per administration was recorded as 100. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 07:39:15
Query 'PER DM CLR: RE-QUERY: Per response 'CORRECTED DOSAGE FROM 40 MG TO 50 MG. However, dose per administration was recorded as 100. Please review and update as appropriate. Thank you.' answered with 'PER SOURCE THE DOSAGE IS 100 MG ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 16:28:21
User opened query 'PER DM CLR: RE-QUERY: Per response 'CORRECTED DOSAGE FROM 40 MG TO 50 MG. However, dose per administration was recorded as 100. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:53:06
User closed query 'Per DM CLR: Please review recorded dose as this is not the usual dose for this medication. Please review and update the dose as appropriate. Otherwise, clarify alternate dose given.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:53:06
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:45:53
User entered '100' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 15:38:46
Query 'Per DM CLR: Please review recorded dose as this is not the usual dose for this medication. Please review and update the dose as appropriate. Otherwise, clarify alternate dose given.' answered with 'CORRECTED DOSAGE FROM 40 MG TO 50 MG' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 14:15:08
User entered '50' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Apr 2021 14:14:27
User opened query 'Per DM CLR: Please review recorded dose as this is not the usual dose for this medication. Please review and update the dose as appropriate. Otherwise, clarify alternate dose given.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 00:03:47
User entered '40'	Tammy Kohn (b) (4) (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'twice daily (BID)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'UN UNK 2016'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:24:15

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:26:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 23:26:43
Data point term sent to Coder	System	21 Oct 2020 23:26:00
User entered 'PANTOPRAZOLE'	Tammy Kohn (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Tammy Kohn (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '40'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:25:39
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'once daily (QD)'	Tammy Kohn (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:25:39
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:25:39
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'UN UNK 2018'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '0'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 23:25:39

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Nov 2020 07:05:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:05:53
Data point term sent to Coder	System	16 Nov 2020 20:19:00
User entered 'OXYGEN'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '2'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Other (OTHER)'	Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User closed query 'Per DM CLR: Please review recorded Unit as it is partially correct. Please note, the dosage delivery of this medication is in Liters per minute or L/Min. Please review and update the recorded unit as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:51:32
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
Query 'Per DM CLR: Please review recorded Unit as it is partially correct. Please note, the dosage delivery of this medication is in Liters per minute or L/Min. Please review and update the recorded unit as appropriate. Otherwise, clarify.' answered with '2 LITERS PER MINUTE' (Site from DM).	Tammy Kohn (b) (4)	08 Apr 2021 14:16:19
User entered 'LITERS PER MINUTE' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 14:16:08
User opened query 'Per DM CLR: Please review recorded Unit as it is partially correct. Please note, the dosage delivery of this medication is in Liters per minute or L/Min. Please review and update the recorded unit as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 00:02:53
User entered 'LITERS'	Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'other (OTHER)'	Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'CONTINUOUSLY'	Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '9 Nov 2020'	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '0'	Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	Traci Hull (b) (4)	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:18:34

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 14:17:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:17:20
Data point term sent to Coder	System	16 Feb 2021 15:49:11
User entered 'TRAMADOL'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'PAIN CONTROL FOR AFTER HIATAL HERNIA SURGERY'	Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '50'	Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'mg (mg)'	Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'as needed (PRN)'	Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '09 Feb 2021'	(b) (4) Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '0'	Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	Traci Hull (b) (4)	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 15:48:36

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:39:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:39:18
Data point term sent to Coder	System	05 Apr 2021 13:38:27
User entered 'AMOXICILLIN'	Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'SINUSITIS'	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '500'	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'three times daily (TID)'	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42
	(b) (4)	

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '19 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '0'	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '29 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:31:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 13:37:42

US3402448

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:24:13

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:59
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:23:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 21:23:25

US3402448

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:24:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:24:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered '9 Feb 2021'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:24:01

US3402448

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:24:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:24:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'HIATAL HERNIA REPAIR'	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:24:01

US3402448

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:24:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:24:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered 'Medical History (MH)'	Tammy Kohn (b) (4)	23 Feb 2021 21:24:01

US3402448

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:24:13

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:24:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:45:53
User entered empty.	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 21:24:01

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'USA-US059-2020-MRNA-1273-P301000017'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Yes (Y)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Yes (Y)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Frank'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Eder'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered '1290 Upper Front Street'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Binghamton'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'NY'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered '13901'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:27
User entered 'US'	System	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Nov 2020 20:35:49
User entered '1'	System	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'USA-US059-2020-MRNA-1273-P301000017'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Yes (Y)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Yes (Y)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Frank'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Eder'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered '1290 Upper Front Street'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Binghamton'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'NY'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered '13901'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:27
User entered 'US'	System	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Nov 2020 20:35:49
User entered '1'	System	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:24:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:27
User entered '17/Nov/2020 08:22'	System	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:24:13

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.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'USA-US059-2020-MRNA-1273-P301000017'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Yes (Y)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Yes (Y)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'No (N)'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Frank'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Eder'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered '1290 Upper Front Street'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'Binghamton'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered 'NY'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:22:41
User entered '13901'	System	17 Nov 2020 13:22:19

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:27
User entered 'US'	System	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Nov 2020 20:35:49
User entered '1'	System	17 Nov 2020 13:22:46

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:24:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:00:27
User entered '25/Nov/2020 15:35'	System	25 Nov 2020 20:35:49

US3402448

Folder: SAE USA-US059-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:24:13

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.	Frank Eder (b) (4)	27 Apr 2021 00:01:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:00:27
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 20:35:49