

US3402288 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:26:32

All time stamps listed in this document are displayed in GMT

US3402288

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

[Participant ID](#)

US3402288

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

US3402288

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3402288

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	42
Age Units	YEARS
Age (Derived)	42
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

US3402288

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Date of Informed Consent (<i>dd MMM yyyy</i>)	8 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3402288

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3402288

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Were any significant conditions reported?

Yes ☒

No ☐

US3402288

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Condition	TYPE II DIABETES
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)	_____

US3402288

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Condition	DIZZINESS
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)	_____

US3402288

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Condition	BILATERAL OVARIAN CYSTS
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3402288

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3402288

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

US3402288

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Condition	ASTHMA
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)	_____

US3402288

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Condition	SEVERE OBESITY
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)	

US3402288

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:44 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 09:44
Height (<i>xxx.x</i>)	166 cm
Weight (<i>xxx.x</i>)	161.0 kg
BMI (<i>xxx.x</i>)	58.42648 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)	

US3402288

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 AUG 2020

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

US3402288

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Date of assessment (dd MMM yyyy) 8 AUG 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 2015

Date of surgery unknown False

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

Date of last menstruation unknown False

US3402288

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3402288

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3402288

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 143110

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 ☒

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Height	ND - Not Done
Weight	ND - Not Done

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

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)	8 AUG 2020
Time of assessment (00:00-23:59)	09:44 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 09:44
Temperature (xxx.x)	98.2 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

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)	8 AUG 2020
Time of assessment (00:00-23:59)	10:53 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 10:53
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3402288

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

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.

US3402288

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

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) 8 AUG 2020

What was the treatment time? (00:00-23:59) 10:22 (24 HR)

Treatment Date and Time (derived) 8 AUG 2020 10:22

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

US3402288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 AUG 2020
Collection time (00:00-23:59)	10:06 (24 HR)
Collection date and time (derived)	8 AUG 2020 10:06

US3402288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Collection date (dd MMM yyyy)			8 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:01	8 AUG 2020 10:01
Nasopharyngeal Swab 2	No		

US3402288

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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

96.5 °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

08 AUG 2020 10:54

PC Open Date & Time

08 AUG 2020 10:42

PC Close Date & Time

08 AUG 2020 13:12

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	08 AUG 2020 18:48
PC Open Date & Time	08 AUG 2020 14:07
PC Close Date & Time	09 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 18:42

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

10 AUG 2020 18:40

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

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

11 AUG 2020 18:50

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 18:32

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

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

13 AUG 2020 18:42

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 18:34

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 10:55

PC Open Date & Time

08 AUG 2020 10:42

PC Close Date & Time

08 AUG 2020 13:12

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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

08 AUG 2020 18:49

PC Open Date & Time

08 AUG 2020 14:07

PC Close Date & Time

09 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

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

09 AUG 2020 18:43

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

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

10 AUG 2020 18:39

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

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

11 AUG 2020 18:49

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

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

12 AUG 2020 18:33

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

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

13 AUG 2020 18:41

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

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

14 AUG 2020 18:33

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 10:56
PC Open Date & Time	08 AUG 2020 10:42
PC Close Date & Time	08 AUG 2020 13:12

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 18:50
PC Open Date & Time	08 AUG 2020 14:07
PC Close Date & Time	09 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2241

EAB) (1725)

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 18:44
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

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 ☒

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 18:39
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2241

EAB) (1725)

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 18:49
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

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

60 of 2241

EAB) (1725)

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 18:32
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

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

62 of 2241

EAB) (1725)

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 18:42
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

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

64 of 2241

EAB) (1725)

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 18:33
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3402288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

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)	8 SEP 2020
Time of assessment (00:00-23:59)	10:08 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 10:08
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)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 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

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 11:36
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3402288

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3402288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 11:01 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 11:01

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

What was the frequency of the study treatment dosing? ONCE

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

US3402288

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	10:55 (24 HR)
Collection date and time (derived)	8 SEP 2020 10:55

US3402288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:00	8 SEP 2020 11:00
Nasopharyngeal Swab 2	No		

US3402288

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 11:21

PC Open Date & Time

08 SEP 2020 11:21

PC Close Date & Time

08 SEP 2020 13:51

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	08 SEP 2020 19:29
PC Open Date & Time	08 SEP 2020 14:46
PC Close Date & Time	09 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

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

98.6 °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

09 SEP 2020 22:30

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

10 SEP 2020 21:15

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

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

99.8 °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

11 SEP 2020 19:18

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

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

99.6 °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

12 SEP 2020 19:46

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

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.

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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

99.6 °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

14 SEP 2020 08:33

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

14 SEP 2020 20:39

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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

08 SEP 2020 11:21

PC Open Date & Time

08 SEP 2020 11:21

PC Close Date & Time

08 SEP 2020 13:51

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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

08 SEP 2020 19:25

PC Open Date & Time

08 SEP 2020 14:46

PC Close Date & Time

09 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

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

09 SEP 2020 22:29

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

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

10 SEP 2020 21:16

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

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

11 SEP 2020 19:15

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

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

12 SEP 2020 19:43

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

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

14 SEP 2020 08:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

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

14 SEP 2020 20:36

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 11:22
PC Open Date & Time	08 SEP 2020 11:21
PC Close Date & Time	08 SEP 2020 13:51

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 19:28
PC Open Date & Time	08 SEP 2020 14:46
PC Close Date & Time	09 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

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 ☒

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 22:29
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

102 of 2241

EAB) (1725)

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 21:15
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

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 ☒

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

106 of 2241

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:44
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

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 ☒

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 08:30
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

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 ☒

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 20:35
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3402288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:53

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:20 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 10:20
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	95 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402288

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

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.

US3402288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 OCT 2020
Collection time (00:00-23:59)	10:25 (24 HR)
Collection date and time (derived)	7 OCT 2020 10:25

US3402288

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:47:54

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 OCT 2020 09:26:29
Patient Cloud Open Date & Time	08 OCT 2020 00:01
Patient Cloud Close Date & Time	12 OCT 2020 23:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 12:10:53

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 19:13:13

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	09 NOV 2020 17:09:18
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 15:00:26
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

23 NOV 2020 15:44:45

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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	30 NOV 2020 11:36:35
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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	09 DEC 2020 23:59:51
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	16 DEC 2020 11:28:31
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

23 DEC 2020 20:54:17

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 14:22:26

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 10:43:41

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 12:32:59

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 16:12:34
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

27 JAN 2021 12:45:27

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 13:13:03

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 13:58:49
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 09:57:50
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 16:20:11

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 09:38:29

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 11:02:33

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 12:43:31

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 10:43:17

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 16:46:29

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	08 APR 2021 08:12:44
Patient Cloud Open Date & Time	05 APR 2021 00:01
Patient Cloud Close Date & Time	09 APR 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 14:33:01

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 09:22:07

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 09:32:18

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Date and time of submission	
Patient Cloud Open Date & Time	03 MAY 2021 00:01
Patient Cloud Close Date & Time	07 MAY 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Date and time of submission	
Patient Cloud Open Date & Time	10 MAY 2021 00:01
Patient Cloud Close Date & Time	14 MAY 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUN 2021 00:01
Patient Cloud Close Date & Time	02 JUL 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 334

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

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

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

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

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

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

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Date and time of submission	
Patient Cloud Open Date & Time	05 JUL 2021 00:01
Patient Cloud Close Date & Time	09 JUL 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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="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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 SEP 2021 00:01
Patient Cloud Close Date & Time	17 SEP 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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="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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 <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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐ Yes ☐

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 <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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	31 DEC 2021 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JAN 2022 00:01
Patient Cloud Close Date & Time	04 FEB 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 565
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 <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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 <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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2022 00:01
Patient Cloud Close Date & Time	24 JUN 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2022 00:01
Patient Cloud Close Date & Time	29 JUL 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Patient Cloud Open Date & Time	15 AUG 2022 00:01
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Patient Cloud Close Date & Time	19 AUG 2022 23:59
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US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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="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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2022 00:01
Patient Cloud Close Date & Time	30 SEP 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 <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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

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

US3402288

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:26:32

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		03 MAR 2021 09:38:20

US3402288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:24:52

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:24:52

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

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

Visit date (dd MMM yyyy)	3 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

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) _____

US3402288

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

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.

US3402288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	3 MAR 2021
Collection time (<i>00:00-23:59</i>)	14:15 (24 HR)
Collection date and time (derived)	3 MAR 2021 14:15

US3402288

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted? Yes ☐
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402288

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:26:32

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"/>

US3402288

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:26:32

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402288

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

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

Visit date (dd MMM yyyy)	07 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3402288

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

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>)	07 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

US3402288

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

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

US3402288

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

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)	07 JAN 2021
Time of assessment (00:00-23:59)	10:51 (24 HR)
Vital Signs Date and Time (derived)	07 JAN 2021 10:51
Temperature (xxx.x)	36.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3402288

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

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)	07 JAN 2021
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	07 JAN 2021 11:55
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3402288

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

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 JAN 2021

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

US3402288

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

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

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) 07 JAN 2021

What was the treatment time? (00:00-23:59) 11:23 (24 HR)

Treatment Date and Time (derived) 07 JAN 2021 11:23

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

US3402288

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 JAN 2021

Collection time (00:00-23:59)

10:43 (24 HR)

Collection date and time (derived)

07 JAN 2021 10:43

US3402288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 JAN 2021
Collection time (00:00 - 23:59)	10:45
Collection Date and Time (derived)	07 JAN 2021 10:45

US3402288

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

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

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)	5 FEB 2021
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 11:10
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

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)	5 FEB 2021
Time of assessment (00:00-23:59)	12:11 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 12:11
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3402288

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 FEB 2021

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

US3402288

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

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) 5 FEB 2021

What was the treatment time? (00:00-23:59) 11:40 (24 HR)

Treatment Date and Time (derived) 5 FEB 2021 11:40

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

US3402288

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402288

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:04:44

Generated On: 09 Jun 2021 17:26:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402288

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

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) _____

US3402288

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

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.

US3402288

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	3 MAR 2021
Collection time (<i>00:00-23:59</i>)	14:15 (24 HR)
Collection date and time (derived)	3 MAR 2021 14:15

US3402288

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:44:01

Generated On: 09 Jun 2021 17:26:32

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

AEID

Adverse event

ABCESS TOOTH

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)

21 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

29 DEC 2020

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

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 2241

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

AEID	USA-US059-2021-MRNA-1273-P30 1000015
Adverse event	ABDOMINAL HERNIA
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)	02 APR 2021
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 APR 2021
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)	02 APR 2021
Hospital Discharge Date (dd MMM yyyy)	11 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2241

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

SUBJECT WAS HOSPITALIZED
FOR ABDOMINAL HERNIA
REPAIR. DURING SURGERY IT
WAS NOTED THAT PART OF
THE BOWEL WAS
INTERTWINED IN THE HERNIA
AND WAS NICKED.COVID
TESTING WAS NEGATIVE.
AWAITING FURTHER MEDICAL
RECORDS FOR MEDICATION
AND PROCEDURES.

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

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

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

Yes ☒

No ☐

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

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

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)

356 of 2241

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

	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"/>

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication TOPAMAX

Prophylaxis Yes ☐
No ☒

Indication DIZZINESS CAUSED FROM
MIGRAINES

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2241

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 50,500

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

TWICE WEEKLY

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

PRODUCTION RELEASE (v12.003

360 of 2241

EAB) (1725)

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2241

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

364 of 2241

EAB) (1725)

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

	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 2017	
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"/>

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

366 of 2241

EAB) (1725)

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication ESTRADIOL

Prophylaxis Yes ☐
No ☒

Indication OVARIAN CYSTS

Dose per administration 1

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

368 of 2241

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication POLYETHYLNE GLYCOL 3350

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 17

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

370 of 2241

EAB) (1725)

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

	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 2017	
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"/>

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

372 of 2241

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

	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 1986	
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"/>

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication ANORO
(UMECLIDINIUM-VILANTEROL)

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 62.5/25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

374 of 2241

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

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

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication ALBUTEROL SULFATE HFA

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 90

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

376 of 2241

EAB) (1725)

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 1998	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication ALBUTEROL SOLUTION

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 2.5/3

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

If dose unit is Other, specify MG/ML

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

378 of 2241

EAB) (1725)

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1998	
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"/>

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication ABCESED TOOTH

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

380 of 2241

EAB) (1725)

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 23:36:06

Generated On: 09 Jun 2021 17:26:32

	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)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	29 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3402288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 23:04:24

Generated On: 09 Jun 2021 17:26:32

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 APR 2021	ABDOMINAL HERNIA REPAIR	Adverse Event	

US3402288

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:26:32

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 ☐

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 22:58:28

Generated On: 09 Jun 2021 17:26:32

SAEID	USA-US059-2021-MRNA-1273-P301000015
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

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 22:58:28

Generated On: 09 Jun 2021 17:26:32

SAEID	USA-US059-2021-MRNA-1273-P301000015
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)	22/APR/2021 09:12
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

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 22:58:28

Generated On: 09 Jun 2021 17:26:32

SAEID	USA-US059-2021-MRNA-1273-P301000015
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)	30/APR/2021 08:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3402288 (Prod: Meridian Clinical Research, LLC)

US3402288

Form: Participant Creation

Generated On: 09 Jun 2021 17:26:32

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:55:11
User entered 'US3402288'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:55:37

US3402288

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:49:44
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:26:55

US3402288

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:49:44
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:55:38

US3402288

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:49:44
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:26:55

US3402288

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'SCRN'	System	08 Aug 2020 14:26:55

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered (b) (6) 1978'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:55:39

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered '42'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'YEARS'	System	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '42'	System	08 Aug 2020 14:27:13

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered 'Female (F)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered 'I'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:32

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:15
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:58:37

US3402288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:32

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:25
User entered '8 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:27:13

US3402288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Aug 2020'	System	08 Aug 2020 14:27:13

US3402288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '2020'	System	08 Aug 2020 14:27:13

US3402288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:32

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:25
User entered 'Amendment 2 (2)'	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:27:13

US3402288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:25
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:27:13

US3402288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:32

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:27:13

US3402288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:32

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:27:13

US3402288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:32

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:25
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:27:13

US3402288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:32

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:25
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:55:38

US3402288

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:32

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'I'	System	08 Aug 2020 14:27:20

US3402288

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:35
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	08 Aug 2020 14:27:20

US3402288

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:26:32

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:50:39
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 15:59:18

US3402288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:00:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:00:31
Data point term sent to Coder	System	09 Aug 2020 16:00:04
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:01

US3402288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 2018'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:01

US3402288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:01

US3402288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:01

US3402288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:01

US3402288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:01

US3402288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 2018'	System	09 Aug 2020 16:00:01

US3402288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '2018'	System	09 Aug 2020 16:00:01

US3402288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:00:01

US3402288

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:00:01

US3402288

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:02:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:02:26
Data point term sent to Coder	System	09 Aug 2020 16:01:05
User entered 'DIZZINESS'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:19

US3402288

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 2018'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:19

US3402288

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:19

US3402288

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:19

US3402288

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:19

US3402288

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:19

US3402288

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 2018'	System	09 Aug 2020 16:00:19

US3402288

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '2018'	System	09 Aug 2020 16:00:19

US3402288

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:00:19

US3402288

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:00:19

US3402288

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:02:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:02:27
Data point term sent to Coder	System	09 Aug 2020 16:01:06
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:44

US3402288

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 2019'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:44

US3402288

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:32

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:44

US3402288

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:44

US3402288

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:44

US3402288

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:00:44

US3402288

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 2019'	System	09 Aug 2020 16:00:44

US3402288

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '2019'	System	09 Aug 2020 16:00:44

US3402288

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:00:44

US3402288

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:00:44

US3402288

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:02:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:02:27
Data point term sent to Coder	System	09 Aug 2020 16:02:06
User entered 'VITAMIN D DEFICIENCY'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:22

US3402288

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:22

US3402288

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:22

US3402288

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:22

US3402288

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:22

US3402288

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:22

US3402288

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 2015'	System	09 Aug 2020 16:01:22

US3402288

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '2015'	System	09 Aug 2020 16:01:22

US3402288

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:01:22

US3402288

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:01:22

US3402288

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:02:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:02:27
Data point term sent to Coder	System	09 Aug 2020 16:02:06
User entered 'HYPERLIPIDEMIA'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:36

US3402288

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 2017'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:36

US3402288

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:36

US3402288

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:36

US3402288

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:36

US3402288

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:36

US3402288

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 2017'	System	09 Aug 2020 16:01:36

US3402288

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '2017'	System	09 Aug 2020 16:01:36

US3402288

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:01:36

US3402288

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:01:36

US3402288

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:02:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:02:27
Data point term sent to Coder	System	09 Aug 2020 16:02:06
User entered 'HYPERTENSION'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:52

US3402288

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:52

US3402288

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:52

US3402288

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:52

US3402288

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:52

US3402288

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:01:52

US3402288

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 2015'	System	09 Aug 2020 16:01:52

US3402288

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '2015'	System	09 Aug 2020 16:01:52

US3402288

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:01:52

US3402288

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:01:52

US3402288

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:45:07
User closed query 'Per source - Bilateral Ovarian Cysts. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:45:00
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Nov 2020 12:40:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Nov 2020 12:40:29
Data point term sent to Coder	System	08 Nov 2020 12:39:38
Query 'Per source - Bilateral Ovarian Cysts. Please verify and update accordingly. ' answered with 'Updated' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:39:38
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:39:32
Coding entries removed.	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:39:32
User entered 'Bilateral OVARIAN CYSTS' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:39:32
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:53:06
User opened query 'Per source - Bilateral Ovarian Cysts. Please verify and update accordingly. ' (Site from CRA).		07 Nov 2020 19:51:48
User closed query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous, as well as location. 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)	06 Oct 2020 14:40:54

US3402288

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:32

Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous, as well as location. 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 'bilateral benign cysts' (Site from DM).	Tammy Kohn (b) (4)	30 Sep 2020 18:42:35
User opened query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous, as well as location. 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)	28 Sep 2020 17:35:17
User coded data point as SOC: Reproductive system and breast disorders, HLG: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 16:04:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 16:04:34
Data point term sent to Coder	System	09 Aug 2020 16:03:07
User entered 'OVARIAN CYSTS'	Tarin Gordon (b) (4)	09 Aug 2020 16:02:16

US3402288

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:02:16

US3402288

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:02:16

US3402288

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	25 Sep 2020 12:46:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Tarin Gordon (b) (4)	09 Aug 2020 16:35:00
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:02:16

US3402288

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User closed query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of Hysterectomy was performed in UN UNK 2015. Please review and update if appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 13:33:08
Query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of Hysterectomy was performed in UN UNK 2015. Please review and update if appropriate. Otherwise, clarify.' answered with 'data updated Hysterectomy removed the ovaries ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Sep 2020 18:48:15
User opened query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of Hysterectomy was performed in UN UNK 2015. Please review and update if appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 17:35:54
User entered 'UN UNK 2015' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Sep 2020 12:46:17
User entered empty; reason for change Data Entry Error	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:35:00
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:02:16

US3402288

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:02:16

US3402288

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 2015'	System	09 Aug 2020 16:02:16

US3402288

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '2015'	System	09 Aug 2020 16:02:16

US3402288

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 2015'	System	25 Sep 2020 12:46:17
User entered empty.	System	09 Aug 2020 16:35:00
User entered 'Jan 2015'	System	09 Aug 2020 16:02:16

US3402288

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '2015'	System	25 Sep 2020 12:46:17
User entered empty.	System	09 Aug 2020 16:35:00
User entered '2015'	System	09 Aug 2020 16:02:16

US3402288

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:47:07
User closed query 'Per source - Complete Hysterectomy. Please verify and update accordingly. (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:47:02
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)	08 Nov 2020 12:41:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Nov 2020 12:41:29
Data point term sent to Coder	System	08 Nov 2020 12:40:39
Query 'Per source - Complete Hysterectomy. Please verify and update accordingly. ' answered with 'Updated' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:40:07
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:40:00
Coding entries removed.	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:40:00
User entered 'Complete HYSTERECTOMY' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:40:00
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:53:06
User opened query 'Per source - Complete Hysterectomy. Please verify and update accordingly. (Site from CRA).		07 Nov 2020 19:52:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:06:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:06:35
Data point term sent to Coder	System	09 Aug 2020 16:05:07
User entered 'HYSTERECTOMY'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:18

PRODUCTION RELEASE (v12.003
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492 of 2241

US3402288

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:18

US3402288

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:18

US3402288

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:18

US3402288

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:18

US3402288

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:18

US3402288

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 2015'	System	09 Aug 2020 16:04:18

US3402288

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '2015'	System	09 Aug 2020 16:04:18

US3402288

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 2015'	System	09 Aug 2020 16:04:18

US3402288

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '2015'	System	09 Aug 2020 16:04:18

US3402288

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:07:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:07:30
Data point term sent to Coder	System	09 Aug 2020 16:05:07
User entered 'CONSTIPATION'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:43

US3402288

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 2017'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:43

US3402288

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:43

US3402288

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:43

US3402288

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:43

US3402288

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:43

US3402288

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 2017'	System	09 Aug 2020 16:04:43

US3402288

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '2017'	System	09 Aug 2020 16:04:43

US3402288

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:04:43

US3402288

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:04:43

US3402288

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:06:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:06:35
Data point term sent to Coder	System	09 Aug 2020 16:05:09
User entered 'ANXIETY'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:56

US3402288

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 1986'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:56

US3402288

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:56

US3402288

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:56

US3402288

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:56

US3402288

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:04:56

US3402288

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 1986'	System	09 Aug 2020 16:04:56

US3402288

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '1986'	System	09 Aug 2020 16:04:56

US3402288

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:04:56

US3402288

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:04:56

US3402288

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:09:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:09:30
Data point term sent to Coder	System	09 Aug 2020 16:09:10
User entered 'ASTHMA'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:08:59

US3402288

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 1998'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:08:59

US3402288

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:08:59

US3402288

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:08:59

US3402288

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:08:59

US3402288

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:08:59

US3402288

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 1998'	System	09 Aug 2020 16:08:59

US3402288

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '1998'	System	09 Aug 2020 16:08:59

US3402288

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:08:59

US3402288

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:08:59

US3402288

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:37:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 16:37:32
Data point term sent to Coder	System	09 Aug 2020 16:36:18
User entered 'SEVERE OBESITY'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:35:43

US3402288

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'UN UNK 1998'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:35:43

US3402288

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:35:43

US3402288

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:35:43

US3402288

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:35:43

US3402288

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:53:06
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:35:43

US3402288

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'Jan 1998'	System	09 Aug 2020 16:35:43

US3402288

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '1998'	System	09 Aug 2020 16:35:43

US3402288

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:35:43

US3402288

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered empty.	System	09 Aug 2020 16:35:43

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:56:20
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:56:20
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Aug 2020 16:11:10
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	09 Aug 2020 16:11:10
User entered '8 Aug 2020' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:11:10
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Aug 2020 16:10:52
User entered '9 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:56:20
User entered '09:44'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered '8 Aug 2020 09:44'	System	09 Aug 2020 16:11:10
User entered '9 Aug 2020 09:44'	System	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:56:20
User entered '166' cm	Tarin Gordon (b) (4)	09 Aug 2020 16:10:52
DataPoint set to visible.	(b) (4) System	08 Aug 2020 14:27:20

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:56:20
User entered '161.0' kg	Tarin Gordon (b) (4)	09 Aug 2020 16:10:52
DataPoint set to visible.	(b) (4) System	08 Aug 2020 14:27:20

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
Amendment Manager: User entered '58.42648'	System	16 Sep 2020 23:48:35
User entered '58.4'	System	09 Aug 2020 16:10:52
DataPoint set to visible.	System	08 Aug 2020 14:27:20

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'kg/m2'	System	09 Aug 2020 16:10:52
DataPoint set to visible.	System	08 Aug 2020 14:27:20

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:00:06
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Un-verified.	Tammy Kohn (b) (4)	20 Dec 2020 17:51:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 17:51:48
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:56:20
User entered '98.2' F	Tarin Gordon (b) (4)	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:00:06
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Un-verified.	Tammy Kohn (b) (4)	20 Dec 2020 17:51:48
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 17:51:48
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:56:20
User entered 'Oral (Oral)'	Tarin Gordon (b) (4)	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:56:20
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:00:06
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Un-verified.	Tammy Kohn (b) (4)	20 Dec 2020 17:51:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 17:51:48
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:56:20
User entered '75'	Tarin Gordon (b) (4)	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'bpm'	System	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:00:06
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Un-verified.	Tammy Kohn (b) (4)	20 Dec 2020 17:51:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 17:51:48
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:56:20
User entered '14'	Tarin Gordon (b) (4)	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'breaths/min'	System	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:00:06
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Un-verified.	Tammy Kohn (b) (4)	20 Dec 2020 17:51:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 17:51:48
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:56:20
User entered '122'	Tarin Gordon (b) (4)	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'mmHg'	System	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:00:06
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Un-verified.	Tammy Kohn (b) (4)	20 Dec 2020 17:51:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 17:51:48
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:56:20
User entered '88'	Tarin Gordon (b) (4)	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User entered 'mmHg'	System	09 Aug 2020 16:10:52

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22

US3402288

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22

US3402288

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:56:53
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:11:20

US3402288

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:56:53
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 12:20:30
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 17:40:35
User entered '8 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:11:20

US3402288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:26:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:58:47
User entered '8 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:12:08

US3402288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:26:32

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:58:47
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:12:08

US3402288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:26:32

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:58:47
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 14:48:04
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' answered with 'PATIENT HAD A HYSTERECTOMY DONE IN 2015' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 11:12:15
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 04:23:29
User entered 'Surgically sterile (SURGICALLY STERILE)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:12:08

US3402288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:26:32

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:58:47
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:12:08

US3402288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:26:32

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:58:47
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:12:08

US3402288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:26:32

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:58:47
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:12:08

US3402288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:58:47
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:12:08

US3402288

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:26:32

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:58:47
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:12:08

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

[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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

[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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

[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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

[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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

[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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered 'I'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

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 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered '0'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:15:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:14
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:01

US3402288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:26
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:16

US3402288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:26
User entered '8 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:16

US3402288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:26
User entered 'Clinic (Clinic)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:16

US3402288

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'VISIT1'	System	09 Aug 2020 16:14:16

US3402288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:37
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:55:40

US3402288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:32

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:37
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:04:05
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:04:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 13:55:40
User entered '143110' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:55:40

US3402288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:37
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 13:55:40

US3402288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:32

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)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:37
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:41

US3402288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:32

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)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:37
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:41

US3402288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:37
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:41

US3402288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:32

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:37
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:41

US3402288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:32

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:37
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:14:41

US3402288

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:32

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:59:37
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:53:58
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	02 Nov 2020 13:32:06
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	02 Nov 2020 13:31:59
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:40:53
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:03:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:34:18

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Un-verified.	Tammy Kohn (b) (4)	20 Dec 2020 17:51:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 17:51:27
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:59:48
User entered '166' cm	Tarin Gordon (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Un-verified.	Tammy Kohn (b) (4)	20 Dec 2020 17:51:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 17:51:27
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:59:50
User entered '161.0' kg	Tarin Gordon (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Un-verified.	Tammy Kohn (b) (4)	20 Dec 2020 17:51:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 17:51:27
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:59:48
User entered '166' cm	Tarin Gordon (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Un-verified.	Tammy Kohn (b) (4)	20 Dec 2020 17:51:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 17:51:27
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:59:50
User entered '161.0' kg	Tarin Gordon (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User accepted default value 'Pre-Dose (PREDOSE)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered '8 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered '09:44'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered '8 Aug 2020 09:44'	System	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered '98.2' F	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered '75'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'bpm'	System	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered '14'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'breaths/min'	System	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered '122'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'mmHg'	System	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered '88'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'mmHg'	System	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Un-verified.	Tammy Kohn (b) (4)	20 Dec 2020 17:51:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 17:51:27
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:59:48
User entered '166' cm	Tarin Gordon (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 20:34:22
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Un-verified.	Tammy Kohn (b) (4)	20 Dec 2020 17:51:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 17:51:27
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 19:59:50
User entered '161.0' kg	Tarin Gordon (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User accepted default value 'Post-Dose (POSTDOSE)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered '8 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 19:25:23
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MIN' (Site from System).	Tarin Gordon (b) (4)	09 Aug 2020 16:18:49
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		09 Aug 2020 16:18:41
User entered '10:53'	Tarin Gordon (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered '8 Aug 2020 10:53'	System	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 10:49:58
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with '96.5 IS CORRECT NO CS/NCS OR AE' (Site from System).	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 13:21:13
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:48:35
User entered '96.5' F	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered '74'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'bpm'	System	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered '14'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'breaths/min'	System	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered '134'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'mmHg'	System	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:02:29
User entered '83'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'mmHg'	System	09 Aug 2020 16:18:41

US3402288

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:45:41
User closed query 'Per source physical exam was performed during screening. Please review and update PE to "No" if applicable.' (Site from CRA). Query 'Per source physical exam was performed during screening. Please review and update PE to "No" if applicable.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:45:35
DataPoint Un-verified.	Jennifer Molstead (b) (4)	08 Nov 2020 12:42:10
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	08 Nov 2020 12:42:03
User opened query 'Per source physical exam was performed during screening. Please review and update PE to "No" if applicable.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 20:02:56
DataPoint Verified.		07 Nov 2020 20:02:45
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 16:18:57

US3402288

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:45:41
DataPoint Un-verified.	Jennifer Molstead (b) (4)	08 Nov 2020 12:42:03
User entered empty; reason for change Per Query Resolution	(b) (4) Jennifer Molstead (b) (4)	08 Nov 2020 12:42:03
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 20:02:45
User entered '8 Aug 2020'	Tarin Gordon (b) (4)	09 Aug 2020 16:18:57

US3402288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:10
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:27:59

US3402288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:10
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:27:59

US3402288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

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)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:10
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:27:59

US3402288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 14:27:59

US3402288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:10
User entered '8 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:27:59

US3402288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:10
User entered '10:22'	Jennifer Molstead (b) (4)	08 Aug 2020 14:27:59

US3402288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered '8 Aug 2020 10:22'	System	08 Aug 2020 14:27:59

US3402288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:10
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4) (b) (4)	08 Aug 2020 14:27:59

US3402288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 20:03:10
User entered 'ONCE'	System	08 Aug 2020 14:27:59

US3402288

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 14:27:59

US3402288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:21
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:19:23

US3402288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:21
User entered '8 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:19:23

US3402288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:21
User entered '10:06'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:19:23

US3402288

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered '8 Aug 2020 10:06'	System	09 Aug 2020 16:19:23

US3402288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:26:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:26
User entered '8 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:19:38

US3402288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:19:38

US3402288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:26
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:19:38

US3402288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:26
User entered '10:01'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:19:38

US3402288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered '8 Aug 2020 10:01'	System	09 Aug 2020 16:19:38

US3402288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tarin Gordon (b) (4)	09 Aug 2020 16:19:38

US3402288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:26
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:19:38

US3402288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:26
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:19:38

US3402288

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered empty.	System	09 Aug 2020 16:19:38

US3402288

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:03:34
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:19:42

US3402288

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'I'	System	09 Aug 2020 16:19:42

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:54:22', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ffb53373-f9b1-439f-a8b7-f205ba401705'	System	08 Aug 2020 14:54:43
User entered 'Yes (Y)'	System	08 Aug 2020 14:54:43

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:54:28', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ffb53373-f9b1-439f-a8b7-f205ba401705'	System	08 Aug 2020 14:54:43
User entered '96.5'	System	08 Aug 2020 14:54:43

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:54:35', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ffb53373-f9b1-439f-a8b7-f205ba401705'	System	08 Aug 2020 14:54:43
User entered 'No (N)'	System	08 Aug 2020 14:54:43

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:54:42', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ffb53373-f9b1-439f-a8b7-f205ba401705'	System	08 Aug 2020 14:54:43
User entered '08 Aug 2020 10:54'	System	08 Aug 2020 14:54:43

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Aug 2020 10:42'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Aug 2020 13:12'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:48:33', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0de4fc88-f132-4580-bb51-46c3bf72a0e1'	System	08 Aug 2020 22:48:57
User entered 'Yes (Y)'	System	08 Aug 2020 22:48:57

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:48:43', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0de4fc88-f132-4580-bb51-46c3bf72a0e1' User entered '97.9'	System	08 Aug 2020 22:48:57
	System	08 Aug 2020 22:48:57

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:48:47', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0de4fc88-f132-4580-bb51-46c3bf72a0e1'	System	08 Aug 2020 22:48:57
User entered 'No (N)'	System	08 Aug 2020 22:48:57

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:48:54', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0de4fc88-f132-4580-bb51-46c3bf72a0e1'	System	08 Aug 2020 22:48:57
User entered '08 Aug 2020 18:48'	System	08 Aug 2020 22:48:57

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Aug 2020 14:07'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 2'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:42:22', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7a61d5a2-6f27-4994-a425-61e8e2b92e91'	System	09 Aug 2020 22:42:51
User entered 'Yes (Y)'	System	09 Aug 2020 22:42:51

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:42:31', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7a61d5a2-6f27-4994-a425-61e8e2b92e91'	System	09 Aug 2020 22:42:51
User entered '98.1'	System	09 Aug 2020 22:42:51

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:42:41', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7a61d5a2-6f27-4994-a425-61e8e2b92e91'	System	09 Aug 2020 22:42:51
User entered 'No (N)'	System	09 Aug 2020 22:42:51

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:42:46', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7a61d5a2-6f27-4994-a425-61e8e2b92e91'	System	09 Aug 2020 22:42:51
User entered '09 Aug 2020 18:42'	System	09 Aug 2020 22:42:51

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 3'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:46', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'b98f6776-9d7d-4206-9819-49ff5c743d21'	System	10 Aug 2020 22:40:08
User entered 'Yes (Y)'	System	10 Aug 2020 22:40:08

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:53', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'b98f6776-9d7d-4206-9819-49ff5c743d21' User entered '97.7'	System	10 Aug 2020 22:40:08

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:58', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'b98f6776-9d7d-4206-9819-49ff5c743d21'	System	10 Aug 2020 22:40:08
User entered 'No (N)'	System	10 Aug 2020 22:40:08

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:40:04', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'b98f6776-9d7d-4206-9819-49ff5c743d21'	System	10 Aug 2020 22:40:08
User entered '10 Aug 2020 18:40'	System	10 Aug 2020 22:40:08

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 4'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:49:36', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '08367442-60bd-4ae6-839c-538e40d0b61b'	System	11 Aug 2020 22:50:24
User entered 'Yes (Y)'	System	11 Aug 2020 22:50:24

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:49:41', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '08367442-60bd-4ae6-839c-538e40d0b61b' User entered '98.4'	System	11 Aug 2020 22:50:24
	System	11 Aug 2020 22:50:24

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:49:44', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '08367442-60bd-4ae6-839c-538e40d0b61b'	System	11 Aug 2020 22:50:24
User entered 'No (N)'	System	11 Aug 2020 22:50:24

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:50:18', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '08367442-60bd-4ae6-839c-538e40d0b61b'	System	11 Aug 2020 22:50:24
User entered '11 Aug 2020 18:50'	System	11 Aug 2020 22:50:24

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 5'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:32:20', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8cf76ff8-1958-4322-bc34-015ce443a932'	System	12 Aug 2020 22:33:02
User entered 'Yes (Y)'	System	12 Aug 2020 22:33:02

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:32:44', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8cf76ff8-1958-4322-bc34-015ce443a932'	System	12 Aug 2020 22:33:02
User entered '97.6'	System	12 Aug 2020 22:33:02

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:32:47', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8cf76ff8-1958-4322-bc34-015ce443a932'	System	12 Aug 2020 22:33:02
User entered 'No (N)'	System	12 Aug 2020 22:33:02

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:32:59', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8cf76ff8-1958-4322-bc34-015ce443a932'	System	12 Aug 2020 22:33:02
User entered '12 Aug 2020 18:32'	System	12 Aug 2020 22:33:02

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 6'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:42:33', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0bcd3501-82ac-43f4-a0e9-b71933fd1572'	System	13 Aug 2020 22:42:58
User entered 'Yes (Y)'	System	13 Aug 2020 22:42:58

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:42:44', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0bcd3501-82ac-43f4-a0e9-b71933fd1572'	System	13 Aug 2020 22:42:58
User entered '98.5'	System	13 Aug 2020 22:42:58

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:42:48', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0bcd3501-82ac-43f4-a0e9-b71933fd1572'	System	13 Aug 2020 22:42:58
User entered 'No (N)'	System	13 Aug 2020 22:42:58

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:42:56', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0bcd3501-82ac-43f4-a0e9-b71933fd1572'	System	13 Aug 2020 22:42:58
User entered '13 Aug 2020 18:42'	System	13 Aug 2020 22:42:58

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 7'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:34:22', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '66d0e557-6c29-4ed2-8282-febe5683e7a5'	System	14 Aug 2020 22:34:59
User entered 'Yes (Y)'	System	14 Aug 2020 22:34:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:34:43', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '66d0e557-6c29-4ed2-8282-febe5683e7a5'	System	14 Aug 2020 22:34:59
User entered '97.9'	System	14 Aug 2020 22:34:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:34:46', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '66d0e557-6c29-4ed2-8282-febe5683e7a5'	System	14 Aug 2020 22:34:59
User entered 'No (N)'	System	14 Aug 2020 22:34:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:34:55', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '66d0e557-6c29-4ed2-8282-febe5683e7a5'	System	14 Aug 2020 22:34:59
User entered '14 Aug 2020 18:34'	System	14 Aug 2020 22:34:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:55:17', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8a47a567-a5f2-4d75-900f-5ea6a1eb393f'	System	08 Aug 2020 14:55:58
User entered 'None (1)'	System	08 Aug 2020 14:55:58

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:55:21', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8a47a567-a5f2-4d75-900f-5ea6a1eb393f'	System	08 Aug 2020 14:55:58
User entered 'No (N)'	System	08 Aug 2020 14:55:58

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:55:25', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8a47a567-a5f2-4d75-900f-5ea6a1eb393f'	System	08 Aug 2020 14:55:58
User entered 'No (N)'	System	08 Aug 2020 14:55:58

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:55:29', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8a47a567-a5f2-4d75-900f-5ea6a1eb393f'	System	08 Aug 2020 14:55:58
User entered 'None (1)'	System	08 Aug 2020 14:55:58

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:55:53', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8a47a567-a5f2-4d75-900f-5ea6a1eb393f' User entered '08 Aug 2020 10:55'	System	08 Aug 2020 14:55:58
	System	08 Aug 2020 14:55:58

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Aug 2020 10:42'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Aug 2020 13:12'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:49:10', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a960b1e-2b4f-4184-b2b4-20db7ed46158'	System	08 Aug 2020 22:49:45
User entered 'None (1)'	System	08 Aug 2020 22:49:45

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:49:14', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a960b1e-2b4f-4184-b2b4-20db7ed46158'	System	08 Aug 2020 22:49:45
User entered 'No (N)'	System	08 Aug 2020 22:49:45

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:49:18', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a960b1e-2b4f-4184-b2b4-20db7ed46158'	System	08 Aug 2020 22:49:45
User entered 'No (N)'	System	08 Aug 2020 22:49:45

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:49:32', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a960b1e-2b4f-4184-b2b4-20db7ed46158'	System	08 Aug 2020 22:49:45
User entered 'None (1)'	System	08 Aug 2020 22:49:45

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:49:41', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a960b1e-2b4f-4184-b2b4-20db7ed46158'	System	08 Aug 2020 22:49:45
User entered '08 Aug 2020 18:49'	System	08 Aug 2020 22:49:45

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Aug 2020 14:07'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 2'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:42:52', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'fdcc094b-60f5-4862-abd6-4a43763c32d3'	System	09 Aug 2020 22:43:34
User entered 'None (1)'	System	09 Aug 2020 22:43:34

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:43:07', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'fdcc094b-60f5-4862-abd6-4a43763c32d3'	System	09 Aug 2020 22:43:34
User entered 'No (N)'	System	09 Aug 2020 22:43:34

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:43:09', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'fdcc094b-60f5-4862-abd6-4a43763c32d3'	System	09 Aug 2020 22:43:34
User entered 'No (N)'	System	09 Aug 2020 22:43:34

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:43:13', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'fdcc094b-60f5-4862-abd6-4a43763c32d3'	System	09 Aug 2020 22:43:34
User entered 'None (1)'	System	09 Aug 2020 22:43:34

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:43:31', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'fdcc094b-60f5-4862-abd6-4a43763c32d3'	System	09 Aug 2020 22:43:34
User entered '09 Aug 2020 18:43'	System	09 Aug 2020 22:43:34

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 3'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:23', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0ff66c16-693e-49c4-a487-f53a18ed005e'	System	10 Aug 2020 22:39:40
User entered 'None (1)'	System	10 Aug 2020 22:39:40

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:27', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0ff66c16-693e-49c4-a487-f53a18ed005e'	System	10 Aug 2020 22:39:40
User entered 'No (N)'	System	10 Aug 2020 22:39:40

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:29', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0ff66c16-693e-49c4-a487-f53a18ed005e'	System	10 Aug 2020 22:39:40
User entered 'No (N)'	System	10 Aug 2020 22:39:40

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:30', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0ff66c16-693e-49c4-a487-f53a18ed005e'	System	10 Aug 2020 22:39:40
User entered 'None (1)'	System	10 Aug 2020 22:39:40

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:36', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0ff66c16-693e-49c4-a487-f53a18ed005e'	System	10 Aug 2020 22:39:40
User entered '10 Aug 2020 18:39'	System	10 Aug 2020 22:39:40

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 4'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:49:07', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c935a386-d9f4-46ee-b213-38c427c7ec06'	System	11 Aug 2020 22:49:41
User entered 'None (1)'	System	11 Aug 2020 22:49:41

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:49:11', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c935a386-d9f4-46ee-b213-38c427c7ec06'	System	11 Aug 2020 22:49:41
User entered 'No (N)'	System	11 Aug 2020 22:49:41

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:49:19', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c935a386-d9f4-46ee-b213-38c427c7ec06'	System	11 Aug 2020 22:49:41
User entered 'No (N)'	System	11 Aug 2020 22:49:41

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:49:21', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c935a386-d9f4-46ee-b213-38c427c7ec06'	System	11 Aug 2020 22:49:41
User entered 'None (1)'	System	11 Aug 2020 22:49:41

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:49:25', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c935a386-d9f4-46ee-b213-38c427c7ec06'	System	11 Aug 2020 22:49:41
User entered '11 Aug 2020 18:49'	System	11 Aug 2020 22:49:41

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 5'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:33:04', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '14bcd4f5-0826-4858-a5b3-47368828ea57'	System	12 Aug 2020 22:33:19
User entered 'None (1)'	System	12 Aug 2020 22:33:19

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:33:06', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '14bcd4f5-0826-4858-a5b3-47368828ea57'	System	12 Aug 2020 22:33:19
User entered 'No (N)'	System	12 Aug 2020 22:33:19

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:33:08', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '14bcd4f5-0826-4858-a5b3-47368828ea57'	System	12 Aug 2020 22:33:19
User entered 'No (N)'	System	12 Aug 2020 22:33:19

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:33:10', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '14bcd4f5-0826-4858-a5b3-47368828ea57'	System	12 Aug 2020 22:33:19
User entered 'None (1)'	System	12 Aug 2020 22:33:19

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:33:16', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '14bcd4f5-0826-4858-a5b3-47368828ea57'	System	12 Aug 2020 22:33:19
User entered '12 Aug 2020 18:33'	System	12 Aug 2020 22:33:19

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 6'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:41:13', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '235fd2b2-3cf5-4f71-a285-465bb6eb3655'	System	13 Aug 2020 22:41:29
User entered 'None (1)'	System	13 Aug 2020 22:41:29

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:41:17', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '235fd2b2-3cf5-4f71-a285-465bb6eb3655'	System	13 Aug 2020 22:41:29
User entered 'No (N)'	System	13 Aug 2020 22:41:29

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:41:19', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '235fd2b2-3cf5-4f71-a285-465bb6eb3655'	System	13 Aug 2020 22:41:29
User entered 'No (N)'	System	13 Aug 2020 22:41:29

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:41:21', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '235fd2b2-3cf5-4f71-a285-465bb6eb3655'	System	13 Aug 2020 22:41:29
User entered 'None (1)'	System	13 Aug 2020 22:41:29

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:41:26', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '235fd2b2-3cf5-4f71-a285-465bb6eb3655'	System	13 Aug 2020 22:41:29
User entered '13 Aug 2020 18:41'	System	13 Aug 2020 22:41:29

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 7'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:13', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '16075321-bd04-4327-9e56-2ffee47c3a57'	System	14 Aug 2020 22:33:25
User entered 'None (1)'	System	14 Aug 2020 22:33:25

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:15', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '16075321-bd04-4327-9e56-2ffee47c3a57'	System	14 Aug 2020 22:33:25
User entered 'No (N)'	System	14 Aug 2020 22:33:25

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:17', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '16075321-bd04-4327-9e56-2ffee47c3a57'	System	14 Aug 2020 22:33:25
User entered 'No (N)'	System	14 Aug 2020 22:33:25

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:18', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '16075321-bd04-4327-9e56-2ffee47c3a57'	System	14 Aug 2020 22:33:25
User entered 'None (1)'	System	14 Aug 2020 22:33:25

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:22', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '16075321-bd04-4327-9e56-2ffee47c3a57'	System	14 Aug 2020 22:33:25
User entered '14 Aug 2020 18:33'	System	14 Aug 2020 22:33:25

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:56:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4485e5a0-2c37-4577-aa95-0db9bfdb87f5'	System	08 Aug 2020 14:56:44
User entered 'None (0)'	System	08 Aug 2020 14:56:44

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:56:02', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4485e5a0-2c37-4577-aa95-0db9bfdb87f5'	System	08 Aug 2020 14:56:44
User entered 'None (0)'	System	08 Aug 2020 14:56:44

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:56:05', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4485e5a0-2c37-4577-aa95-0db9bfdb87f5'	System	08 Aug 2020 14:56:44
User entered 'None (0)'	System	08 Aug 2020 14:56:44

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:56:08', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4485e5a0-2c37-4577-aa95-0db9bfdb87f5'	System	08 Aug 2020 14:56:44
User entered 'None (0)'	System	08 Aug 2020 14:56:44

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:56:12', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4485e5a0-2c37-4577-aa95-0db9bfdb87f5'	System	08 Aug 2020 14:56:44
User entered 'None (0)'	System	08 Aug 2020 14:56:44

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:56:14', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4485e5a0-2c37-4577-aa95-0db9bfdb87f5'	System	08 Aug 2020 14:56:44
User entered 'None (0)'	System	08 Aug 2020 14:56:44

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:56:30', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4485e5a0-2c37-4577-aa95-0db9bfdb87f5'	System	08 Aug 2020 14:56:44
User entered 'No (N)'	System	08 Aug 2020 14:56:44

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T10:56:41', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4485e5a0-2c37-4577-aa95-0db9bfdb87f5'	System	08 Aug 2020 14:56:44
User entered '08 Aug 2020 10:56'	System	08 Aug 2020 14:56:44

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Aug 2020 10:42'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Aug 2020 13:12'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:49:50', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4032717b-e879-409d-9128-0648490bff39'	System	08 Aug 2020 22:50:22
User entered 'None (0)'	System	08 Aug 2020 22:50:22

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:49:53', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4032717b-e879-409d-9128-0648490bff39'	System	08 Aug 2020 22:50:22
User entered 'None (0)'	System	08 Aug 2020 22:50:22

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:49:57', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4032717b-e879-409d-9128-0648490bff39'	System	08 Aug 2020 22:50:22
User entered 'None (0)'	System	08 Aug 2020 22:50:22

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:50:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4032717b-e879-409d-9128-0648490bff39'	System	08 Aug 2020 22:50:22
User entered 'None (0)'	System	08 Aug 2020 22:50:22

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:50:02', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4032717b-e879-409d-9128-0648490bff39'	System	08 Aug 2020 22:50:22
User entered 'None (0)'	System	08 Aug 2020 22:50:22

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:50:04', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4032717b-e879-409d-9128-0648490bff39'	System	08 Aug 2020 22:50:22
User entered 'None (0)'	System	08 Aug 2020 22:50:22

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:50:13', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4032717b-e879-409d-9128-0648490bff39'	System	08 Aug 2020 22:50:22
User entered 'No (N)'	System	08 Aug 2020 22:50:22

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-08T18:50:20', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4032717b-e879-409d-9128-0648490bff39'	System	08 Aug 2020 22:50:22
User entered '08 Aug 2020 18:50'	System	08 Aug 2020 22:50:22

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Aug 2020 14:07'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 2'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:43:43', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '687958ec-4e44-4484-bbed-9bf41fdf567c'	System	09 Aug 2020 22:44:27
User entered 'None (0)'	System	09 Aug 2020 22:44:27

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:43:45', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '687958ec-4e44-4484-bbed-9bf41fdf567c'	System	09 Aug 2020 22:44:27
User entered 'None (0)'	System	09 Aug 2020 22:44:27

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:43:48', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '687958ec-4e44-4484-bbed-9bf41fdf567c'	System	09 Aug 2020 22:44:27
User entered 'None (0)'	System	09 Aug 2020 22:44:27

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:43:50', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '687958ec-4e44-4484-bbed-9bf41fdf567c'	System	09 Aug 2020 22:44:27
User entered 'None (0)'	System	09 Aug 2020 22:44:27

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:43:52', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '687958ec-4e44-4484-bbed-9bf41fdf567c'	System	09 Aug 2020 22:44:27
User entered 'None (0)'	System	09 Aug 2020 22:44:27

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:43:54', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '687958ec-4e44-4484-bbed-9bf41fdf567c'	System	09 Aug 2020 22:44:27
User entered 'None (0)'	System	09 Aug 2020 22:44:27

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:44:05', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '687958ec-4e44-4484-bbed-9bf41fdf567c'	System	09 Aug 2020 22:44:27
User entered 'No (N)'	System	09 Aug 2020 22:44:27

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-09T18:44:25', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '687958ec-4e44-4484-bbed-9bf41fdf567c'	System	09 Aug 2020 22:44:27
User entered '09 Aug 2020 18:44'	System	09 Aug 2020 22:44:27

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 3'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:38:55', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '13e7dfbd-5c5b-4f9b-9103-7157be8a7c71'	System	10 Aug 2020 22:39:25
User entered 'None (0)'	System	10 Aug 2020 22:39:25

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:38:57', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '13e7dfbd-5c5b-4f9b-9103-7157be8a7c71'	System	10 Aug 2020 22:39:25
User entered 'None (0)'	System	10 Aug 2020 22:39:25

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '13e7dfbd-5c5b-4f9b-9103-7157be8a7c71'	System	10 Aug 2020 22:39:25
User entered 'None (0)'	System	10 Aug 2020 22:39:25

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:02', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '13e7dfbd-5c5b-4f9b-9103-7157be8a7c71'	System	10 Aug 2020 22:39:25
User entered 'None (0)'	System	10 Aug 2020 22:39:25

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:04', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '13e7dfbd-5c5b-4f9b-9103-7157be8a7c71'	System	10 Aug 2020 22:39:25
User entered 'None (0)'	System	10 Aug 2020 22:39:25

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:06', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '13e7dfbd-5c5b-4f9b-9103-7157be8a7c71'	System	10 Aug 2020 22:39:25
User entered 'None (0)'	System	10 Aug 2020 22:39:25

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:10', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '13e7dfbd-5c5b-4f9b-9103-7157be8a7c71'	System	10 Aug 2020 22:39:25
User entered 'No (N)'	System	10 Aug 2020 22:39:25

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-10T18:39:18', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '13e7dfbd-5c5b-4f9b-9103-7157be8a7c71'	System	10 Aug 2020 22:39:25
User entered '10 Aug 2020 18:39'	System	10 Aug 2020 22:39:25

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 4'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:48:40', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '38c0cf63-935f-4735-9760-9ada61096656'	System	11 Aug 2020 22:49:03
User entered 'None (0)'	System	11 Aug 2020 22:49:03

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:48:42', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '38c0cf63-935f-4735-9760-9ada61096656'	System	11 Aug 2020 22:49:03
User entered 'None (0)'	System	11 Aug 2020 22:49:03

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:48:44', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '38c0cf63-935f-4735-9760-9ada61096656'	System	11 Aug 2020 22:49:03
User entered 'None (0)'	System	11 Aug 2020 22:49:03

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:48:45', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '38c0cf63-935f-4735-9760-9ada61096656'	System	11 Aug 2020 22:49:03
User entered 'None (0)'	System	11 Aug 2020 22:49:03

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:48:47', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '38c0cf63-935f-4735-9760-9ada61096656'	System	11 Aug 2020 22:49:03
User entered 'None (0)'	System	11 Aug 2020 22:49:03

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:48:49', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '38c0cf63-935f-4735-9760-9ada61096656'	System	11 Aug 2020 22:49:03
User entered 'None (0)'	System	11 Aug 2020 22:49:03

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:48:51', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '38c0cf63-935f-4735-9760-9ada61096656'	System	11 Aug 2020 22:49:03
User entered 'No (N)'	System	11 Aug 2020 22:49:03

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-11T18:49:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '38c0cf63-935f-4735-9760-9ada61096656'	System	11 Aug 2020 22:49:03
User entered '11 Aug 2020 18:49'	System	11 Aug 2020 22:49:03

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 5'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:31:53', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '72776a4f-86ba-48ae-8074-04377731435f'	System	12 Aug 2020 22:32:17
User entered 'None (0)'	System	12 Aug 2020 22:32:17

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:31:55', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '72776a4f-86ba-48ae-8074-04377731435f' User entered 'None (0)'	System	12 Aug 2020 22:32:17
	System	12 Aug 2020 22:32:17

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:31:56', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '72776a4f-86ba-48ae-8074-04377731435f' User entered 'None (0)'	System	12 Aug 2020 22:32:17
	System	12 Aug 2020 22:32:17

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:31:58', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '72776a4f-86ba-48ae-8074-04377731435f' User entered 'None (0)'	System	12 Aug 2020 22:32:17
	System	12 Aug 2020 22:32:17

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:32:01', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '72776a4f-86ba-48ae-8074-04377731435f' User entered 'None (0)'	System	12 Aug 2020 22:32:17
	System	12 Aug 2020 22:32:17

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:32:05', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '72776a4f-86ba-48ae-8074-04377731435f'	System	12 Aug 2020 22:32:17
User entered 'None (0)'	System	12 Aug 2020 22:32:17

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:32:08', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '72776a4f-86ba-48ae-8074-04377731435f'	System	12 Aug 2020 22:32:17
User entered 'No (N)'	System	12 Aug 2020 22:32:17

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-12T18:32:13', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '72776a4f-86ba-48ae-8074-04377731435f'	System	12 Aug 2020 22:32:17
User entered '12 Aug 2020 18:32'	System	12 Aug 2020 22:32:17

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 6'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:41:29', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c8ddb1ca-69c7-471a-bb20-0d38e7f3b552'	System	13 Aug 2020 22:42:05
User entered 'None (0)'	System	13 Aug 2020 22:42:05

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:41:31', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c8ddb1ca-69c7-471a-bb20-0d38e7f3b552'	System	13 Aug 2020 22:42:05
User entered 'None (0)'	System	13 Aug 2020 22:42:05

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:41:34', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c8ddb1ca-69c7-471a-bb20-0d38e7f3b552'	System	13 Aug 2020 22:42:05
User entered 'None (0)'	System	13 Aug 2020 22:42:05

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:41:36', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c8ddb1ca-69c7-471a-bb20-0d38e7f3b552'	System	13 Aug 2020 22:42:05
User entered 'None (0)'	System	13 Aug 2020 22:42:05

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:41:39', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c8ddb1ca-69c7-471a-bb20-0d38e7f3b552'	System	13 Aug 2020 22:42:05
User entered 'None (0)'	System	13 Aug 2020 22:42:05

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:41:43', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c8ddb1ca-69c7-471a-bb20-0d38e7f3b552'	System	13 Aug 2020 22:42:05
User entered 'None (0)'	System	13 Aug 2020 22:42:05

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:41:47', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c8ddb1ca-69c7-471a-bb20-0d38e7f3b552'	System	13 Aug 2020 22:42:05
User entered 'No (N)'	System	13 Aug 2020 22:42:05

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-13T18:42:03', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c8ddb1ca-69c7-471a-bb20-0d38e7f3b552'	System	13 Aug 2020 22:42:05
User entered '13 Aug 2020 18:42'	System	13 Aug 2020 22:42:05

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 7'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:26', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '5ca7595e-2b6e-4829-a2ec-11c76194ae09'	System	14 Aug 2020 22:33:53
User entered 'None (0)'	System	14 Aug 2020 22:33:53

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:28', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '5ca7595e-2b6e-4829-a2ec-11c76194ae09'	System	14 Aug 2020 22:33:53
User entered 'None (0)'	System	14 Aug 2020 22:33:53

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:29', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '5ca7595e-2b6e-4829-a2ec-11c76194ae09'	System	14 Aug 2020 22:33:53
User entered 'None (0)'	System	14 Aug 2020 22:33:53

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:31', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '5ca7595e-2b6e-4829-a2ec-11c76194ae09'	System	14 Aug 2020 22:33:53
User entered 'None (0)'	System	14 Aug 2020 22:33:53

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:32', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '5ca7595e-2b6e-4829-a2ec-11c76194ae09'	System	14 Aug 2020 22:33:53
User entered 'None (0)'	System	14 Aug 2020 22:33:53

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:34', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '5ca7595e-2b6e-4829-a2ec-11c76194ae09'	System	14 Aug 2020 22:33:53
User entered 'None (0)'	System	14 Aug 2020 22:33:53

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:37', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '5ca7595e-2b6e-4829-a2ec-11c76194ae09'	System	14 Aug 2020 22:33:53
User entered 'No (N)'	System	14 Aug 2020 22:33:53

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-08-14T18:33:52', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '5ca7595e-2b6e-4829-a2ec-11c76194ae09'	System	14 Aug 2020 22:33:53
User entered '14 Aug 2020 18:33'	System	14 Aug 2020 22:33:53

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 14:27:59

US3402288

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:59
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Aug 2020 17:57:49

US3402288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:59
User entered '15 Aug 2020'	Jennifer Molstead (b) (4)	24 Aug 2020 17:57:49

US3402288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:59
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4) (b) (4)	24 Aug 2020 17:57:49

US3402288

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 20:16:59
User entered empty.	Jennifer Molstead (b) (4)	24 Aug 2020 17:57:49

US3402288

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:17:13
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Aug 2020 17:58:04

US3402288

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'I'	System	24 Aug 2020 17:58:04

US3402288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:17:26
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Aug 2020 17:58:48

US3402288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:17:26
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	24 Aug 2020 17:58:48

US3402288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:17:26
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4)	24 Aug 2020 17:58:48

US3402288

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:17:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Aug 2020 17:58:48

US3402288

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:17:36
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Aug 2020 17:58:52

US3402288

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered '1'	System	24 Aug 2020 17:58:52

US3402288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:16:57
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Aug 2020 17:33:05

US3402288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:16:57
User entered '29 Aug 2020'	Traci Hull (b) (4) (b) (4)	29 Aug 2020 17:33:05

US3402288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:16:57
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	29 Aug 2020 17:33:05

US3402288

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:16:57
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Aug 2020 17:33:05

US3402288

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:17:03
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Aug 2020 17:33:09

US3402288

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'I'	System	29 Aug 2020 17:33:09

US3402288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:17:59
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:40:35

US3402288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:17:59
User entered '8 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:40:35

US3402288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:17:59
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:40:35

US3402288

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'VISIT2'	System	08 Sep 2020 17:40:35

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '8 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '10:08'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered '8 Sep 2020 10:08'	System	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '36.7' C	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered empty.	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '96'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'bpm'	System	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '16'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'breaths/min'	System	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '128'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'mmHg'	System	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '82'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'mmHg'	System	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '8 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '11:36'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered '8 Sep 2020 11:36'	System	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '36.2' C	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered empty.	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '84'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'bpm'	System	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '18'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'breaths/min'	System	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '130'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'mmHg'	System	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:05
User entered '78'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'mmHg'	System	08 Sep 2020 17:42:05

US3402288

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:17
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:11

US3402288

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:17
User entered '8 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:11

US3402288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:06:00

US3402288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:30
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:06:00

US3402288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

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)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:30
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:06:00

US3402288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 15:06:00

US3402288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:30
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 15:06:00

US3402288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:30
User entered '11:01'	(b) (4), (b) (6)	08 Sep 2020 15:06:00

US3402288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered '8 Sep 2020 11:01'	System	08 Sep 2020 15:06:00

US3402288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:30
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Sep 2020 15:06:00

US3402288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:19:30
User entered 'ONCE'	System	08 Sep 2020 15:06:00

US3402288

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 15:06:00

US3402288

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:37
User closed query 'Per GCL Lab Reconciliation: Per GCL, no immunogenicity sample was received for the Visit 2 Day 29 on 08SEP2020. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 12:15:36
Query 'Per GCL Lab Reconciliation: Per GCL, no immunogenicity sample was received for the Visit 2 Day 29 on 08SEP2020. Please clarify and update as appropriate.' answered with 'THE INFORMATION IS CORRECT. THE LAB TECH HAS ALREADY TAKEN CARE OF THE SAMPLE ISSUE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	02 Nov 2020 13:51:17
User opened query 'Per GCL Lab Reconciliation: Per GCL, no immunogenicity sample was received for the Visit 2 Day 29 on 08SEP2020. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 23:03:32
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:43

US3402288

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:37
User entered '8 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:43

US3402288

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:37
User entered '10:55'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:42:43

US3402288

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered '8 Sep 2020 10:55'	System	08 Sep 2020 17:42:43

US3402288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:26:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:43
User closed query 'Per GCL Lab recon: Swab: Sample collection date 08-SEP-2020 is recorded under Visit 2 Day 29; however, corresponding swab sample is missing in PPD portal Kindly confirm if swab sample was collected on 08-SEP-2020 for Visit 2 Day 29 to be updated in PPD portal.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:20:44
Query 'Per GCL Lab recon: Swab: Sample collection date 08-SEP-2020 is recorded under Visit 2 Day 29; however, corresponding swab sample is missing in PPD portal Kindly confirm if swab sample was collected on 08-SEP-2020 for Visit 2 Day 29 to be updated in PPD portal.' answered with 'THE SWAB SAMPLE WAS COLLECTED ON 08 SEP 2020 AND CONFIRMED TO BE SENT TO PPD. THE LAB IS WORKING ON THIS TO CORRECT ANY ERRORS.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 15:08:06
User opened query 'Per GCL Lab recon: Swab: Sample collection date 08-SEP-2020 is recorded under Visit 2 Day 29; however, corresponding swab sample is missing in PPD portal Kindly confirm if swab sample was collected on 08-SEP-2020 for Visit 2 Day 29 to be updated in PPD portal.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:06:11
User entered '8 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:43:08

US3402288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:43:08

US3402288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:43
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:43:08

US3402288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:43
User entered '11:00'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:43:08

US3402288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered '8 Sep 2020 11:00'	System	08 Sep 2020 17:43:08

US3402288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:43:08

US3402288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:43
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:43:08

US3402288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:43
User entered empty.	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:43:08

US3402288

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered empty.	System	08 Sep 2020 17:43:08

US3402288

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:19:51
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	08 Sep 2020 17:43:13

US3402288

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered '1'	System	08 Sep 2020 17:43:13

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:21:14', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '667f8966-dfed-455e-a9b6-a055f0f7326b'	System	08 Sep 2020 15:21:32
User entered 'Yes (Y)'	System	08 Sep 2020 15:21:32

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:21:22', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '667f8966-dfed-455e-a9b6-a055f0f7326b' User entered '97.1'	System	08 Sep 2020 15:21:32

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:21:24', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '667f8966-dfed-455e-a9b6-a055f0f7326b'	System	08 Sep 2020 15:21:32
User entered 'No (N)'	System	08 Sep 2020 15:21:32

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:21:28', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '667f8966-dfed-455e-a9b6-a055f0f7326b'	System	08 Sep 2020 15:21:32
User entered '08 Sep 2020 11:21'	System	08 Sep 2020 15:21:32

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Sep 2020 11:21'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Sep 2020 13:51'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:29:03', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '9ef8c6ac-01e9-4454-9a17-11d82a7ff61d'	System	08 Sep 2020 23:29:17
User entered 'Yes (Y)'	System	08 Sep 2020 23:29:17

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:29:08', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '9ef8c6ac-01e9-4454-9a17-11d82a7ff61d'	System	08 Sep 2020 23:29:17
User entered '97.6'	System	08 Sep 2020 23:29:17

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:29:11', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '9ef8c6ac-01e9-4454-9a17-11d82a7ff61d'	System	08 Sep 2020 23:29:17
User entered 'No (N)'	System	08 Sep 2020 23:29:17

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:29:14', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '9ef8c6ac-01e9-4454-9a17-11d82a7ff61d'	System	08 Sep 2020 23:29:17
User entered '08 Sep 2020 19:29'	System	08 Sep 2020 23:29:17

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Sep 2020 14:46'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 2'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:29:51', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7a4546bc-bff5-45ac-9c1c-59783e61b512'	System	10 Sep 2020 02:30:28
User entered 'Yes (Y)'	System	10 Sep 2020 02:30:28

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:30:15', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7a4546bc-bff5-45ac-9c1c-59783e61b512'	System	10 Sep 2020 02:30:28
User entered '98.6'	System	10 Sep 2020 02:30:28

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:30:18', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7a4546bc-bff5-45ac-9c1c-59783e61b512'	System	10 Sep 2020 02:30:28
User entered 'No (N)'	System	10 Sep 2020 02:30:28

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:30:24', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7a4546bc-bff5-45ac-9c1c-59783e61b512'	System	10 Sep 2020 02:30:28
User entered '09 Sep 2020 22:30'	System	10 Sep 2020 02:30:28

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 3'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:14:31', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a3855717-7d80-455f-8e6a-0caba268fa41'	System	11 Sep 2020 01:15:13
User entered 'Yes (Y)'	System	11 Sep 2020 01:15:13

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:15:02', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a3855717-7d80-455f-8e6a-0caba268fa41'	System	11 Sep 2020 01:15:13
User entered '98.6'	System	11 Sep 2020 01:15:13

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:15:06', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a3855717-7d80-455f-8e6a-0caba268fa41'	System	11 Sep 2020 01:15:13
User entered 'No (N)'	System	11 Sep 2020 01:15:13

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:15:11', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a3855717-7d80-455f-8e6a-0caba268fa41'	System	11 Sep 2020 01:15:13
User entered '10 Sep 2020 21:15'	System	11 Sep 2020 01:15:13

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 4'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:17:12', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '60582c2e-9cdd-407a-808d-b81ea1568b4f'	System	11 Sep 2020 23:18:11
User entered 'Yes (Y)'	System	11 Sep 2020 23:18:11

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:17:57', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '60582c2e-9cdd-407a-808d-b81ea1568b4f' User entered '99.8'	System	11 Sep 2020 23:18:11

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:18:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '60582c2e-9cdd-407a-808d-b81ea1568b4f'	System	11 Sep 2020 23:18:11
User entered 'No (N)'	System	11 Sep 2020 23:18:11

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:18:08', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '60582c2e-9cdd-407a-808d-b81ea1568b4f'	System	11 Sep 2020 23:18:11
User entered '11 Sep 2020 19:18'	System	11 Sep 2020 23:18:11

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 5'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:44:59', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ee802f88-0362-46d3-8b13-35618996b645'	System	12 Sep 2020 23:46:10
User entered 'Yes (Y)'	System	12 Sep 2020 23:46:10

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:45:55', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ee802f88-0362-46d3-8b13-35618996b645'	System	12 Sep 2020 23:46:10
User entered '99.6'	System	12 Sep 2020 23:46:10

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:45:58', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ee802f88-0362-46d3-8b13-35618996b645'	System	12 Sep 2020 23:46:10
User entered 'No (N)'	System	12 Sep 2020 23:46:10

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:46:05', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ee802f88-0362-46d3-8b13-35618996b645'	System	12 Sep 2020 23:46:10
User entered '12 Sep 2020 19:46'	System	12 Sep 2020 23:46:10

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 6'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:32:36', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0be7e8f3-92e3-49be-86f8-9b923b9f9673'	System	14 Sep 2020 12:33:12
User entered 'Yes (Y)'	System	14 Sep 2020 12:33:12

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:32:54', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0be7e8f3-92e3-49be-86f8-9b923b9f9673' User entered '99.6'	System	14 Sep 2020 12:33:12

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:32:57', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0be7e8f3-92e3-49be-86f8-9b923b9f9673'	System	14 Sep 2020 12:33:12
User entered 'No (N)'	System	14 Sep 2020 12:33:12

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:33:10', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '0be7e8f3-92e3-49be-86f8-9b923b9f9673'	System	14 Sep 2020 12:33:12
User entered '14 Sep 2020 08:33'	System	14 Sep 2020 12:33:12

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 7'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:37:46', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7e2f94bb-57dd-495c-8c1b-0937636937ce'	System	15 Sep 2020 00:39:58
User entered 'Yes (Y)'	System	15 Sep 2020 00:39:58

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:39:47', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7e2f94bb-57dd-495c-8c1b-0937636937ce'	System	15 Sep 2020 00:39:58
User entered '98.6'	System	15 Sep 2020 00:39:58

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:38:49', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7e2f94bb-57dd-495c-8c1b-0937636937ce'	System	15 Sep 2020 00:39:58
User entered 'No (N)'	System	15 Sep 2020 00:39:58

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:39:55', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7e2f94bb-57dd-495c-8c1b-0937636937ce'	System	15 Sep 2020 00:39:58
User entered '14 Sep 2020 20:39'	System	15 Sep 2020 00:39:58

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:21:34', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8cfa9505-22cb-478f-9b27-1a82c0dea67f'	System	08 Sep 2020 15:21:49
User entered 'None (1)'	System	08 Sep 2020 15:21:49

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:21:37', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8cfa9505-22cb-478f-9b27-1a82c0dea67f'	System	08 Sep 2020 15:21:49
User entered 'No (N)'	System	08 Sep 2020 15:21:49

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:21:40', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8cfa9505-22cb-478f-9b27-1a82c0dea67f'	System	08 Sep 2020 15:21:49
User entered 'No (N)'	System	08 Sep 2020 15:21:49

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:21:42', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8cfa9505-22cb-478f-9b27-1a82c0dea67f'	System	08 Sep 2020 15:21:49
User entered 'None (1)'	System	08 Sep 2020 15:21:49

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:21:45', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '8cfa9505-22cb-478f-9b27-1a82c0dea67f'	System	08 Sep 2020 15:21:49
User entered '08 Sep 2020 11:21'	System	08 Sep 2020 15:21:49

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Sep 2020 11:21'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Sep 2020 13:51'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:25:36', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'eacc0d4d-8360-4319-8b20-661890f3053c'	System	08 Sep 2020 23:25:49
User entered 'None (1)'	System	08 Sep 2020 23:25:49

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:24:29', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'eacc0d4d-8360-4319-8b20-661890f3053c'	System	08 Sep 2020 23:25:49
User entered 'No (N)'	System	08 Sep 2020 23:25:49

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:25:38', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'eacc0d4d-8360-4319-8b20-661890f3053c'	System	08 Sep 2020 23:25:49
User entered 'No (N)'	System	08 Sep 2020 23:25:49

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:25:42', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'eacc0d4d-8360-4319-8b20-661890f3053c'	System	08 Sep 2020 23:25:49
User entered 'None (1)'	System	08 Sep 2020 23:25:49

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:25:47', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'eacc0d4d-8360-4319-8b20-661890f3053c'	System	08 Sep 2020 23:25:49
User entered '08 Sep 2020 19:25'	System	08 Sep 2020 23:25:49

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Sep 2020 14:46'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 2'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:29:33', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '6be9dcdc-88e9-4495-8ef2-056e768b0f0d'	System	10 Sep 2020 02:29:47
User entered 'None (1)'	System	10 Sep 2020 02:29:47

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:29:36', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '6be9dcdc-88e9-4495-8ef2-056e768b0f0d'	System	10 Sep 2020 02:29:47
User entered 'No (N)'	System	10 Sep 2020 02:29:47

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:29:38', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '6be9dcdc-88e9-4495-8ef2-056e768b0f0d'	System	10 Sep 2020 02:29:47
User entered 'No (N)'	System	10 Sep 2020 02:29:47

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:29:40', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '6be9dcdc-88e9-4495-8ef2-056e768b0f0d'	System	10 Sep 2020 02:29:47
User entered 'None (1)'	System	10 Sep 2020 02:29:47

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:29:45', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '6be9dcdc-88e9-4495-8ef2-056e768b0f0d'	System	10 Sep 2020 02:29:47
User entered '09 Sep 2020 22:29'	System	10 Sep 2020 02:29:47

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 3'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:15:56', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ac47215c-9a15-45b4-8beb-5793361af664'	System	11 Sep 2020 01:16:20
User entered 'None (1)'	System	11 Sep 2020 01:16:20

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:16:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ac47215c-9a15-45b4-8beb-5793361af664'	System	11 Sep 2020 01:16:20
User entered 'No (N)'	System	11 Sep 2020 01:16:20

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:16:03', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ac47215c-9a15-45b4-8beb-5793361af664'	System	11 Sep 2020 01:16:20
User entered 'No (N)'	System	11 Sep 2020 01:16:20

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:16:12', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ac47215c-9a15-45b4-8beb-5793361af664'	System	11 Sep 2020 01:16:20
User entered 'None (1)'	System	11 Sep 2020 01:16:20

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:16:16', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ac47215c-9a15-45b4-8beb-5793361af664'	System	11 Sep 2020 01:16:20
User entered '10 Sep 2020 21:16'	System	11 Sep 2020 01:16:20

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 4'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:11', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '37d0bad9-61e1-4252-979f-f23ac35f7114'	System	11 Sep 2020 23:15:35
User entered 'None (1)'	System	11 Sep 2020 23:15:35

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:14', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '37d0bad9-61e1-4252-979f-f23ac35f7114'	System	11 Sep 2020 23:15:35
User entered 'No (N)'	System	11 Sep 2020 23:15:35

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:19', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '37d0bad9-61e1-4252-979f-f23ac35f7114'	System	11 Sep 2020 23:15:35
User entered 'No (N)'	System	11 Sep 2020 23:15:35

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:26', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '37d0bad9-61e1-4252-979f-f23ac35f7114'	System	11 Sep 2020 23:15:35
User entered 'None (1)'	System	11 Sep 2020 23:15:35

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:30', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '37d0bad9-61e1-4252-979f-f23ac35f7114'	System	11 Sep 2020 23:15:35
User entered '11 Sep 2020 19:15'	System	11 Sep 2020 23:15:35

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 5'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:43:09', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '6a4941e1-a3fb-4338-9071-e3f60b74bb68'	System	12 Sep 2020 23:43:30
User entered 'None (1)'	System	12 Sep 2020 23:43:30

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:43:12', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '6a4941e1-a3fb-4338-9071-e3f60b74bb68'	System	12 Sep 2020 23:43:30
User entered 'No (N)'	System	12 Sep 2020 23:43:30

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:43:14', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '6a4941e1-a3fb-4338-9071-e3f60b74bb68'	System	12 Sep 2020 23:43:30
User entered 'No (N)'	System	12 Sep 2020 23:43:30

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:43:16', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '6a4941e1-a3fb-4338-9071-e3f60b74bb68'	System	12 Sep 2020 23:43:30
User entered 'None (1)'	System	12 Sep 2020 23:43:30

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:43:27', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '6a4941e1-a3fb-4338-9071-e3f60b74bb68'	System	12 Sep 2020 23:43:30
User entered '12 Sep 2020 19:43'	System	12 Sep 2020 23:43:30

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 6'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:31:04', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '674d2373-a6ea-4c2e-ba73-368a33296055'	System	14 Sep 2020 12:31:27
User entered 'None (1)'	System	14 Sep 2020 12:31:27

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:31:06', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '674d2373-a6ea-4c2e-ba73-368a33296055'	System	14 Sep 2020 12:31:27
User entered 'No (N)'	System	14 Sep 2020 12:31:27

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:31:08', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '674d2373-a6ea-4c2e-ba73-368a33296055'	System	14 Sep 2020 12:31:27
User entered 'No (N)'	System	14 Sep 2020 12:31:27

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:31:10', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '674d2373-a6ea-4c2e-ba73-368a33296055'	System	14 Sep 2020 12:31:27
User entered 'None (1)'	System	14 Sep 2020 12:31:27

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:31:15', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '674d2373-a6ea-4c2e-ba73-368a33296055'	System	14 Sep 2020 12:31:27
User entered '14 Sep 2020 08:31'	System	14 Sep 2020 12:31:27

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 7'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:35:54', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '67cb05c0-196e-4661-9f8b-ba8bb0547c85'	System	15 Sep 2020 00:36:07
User entered 'None (1)'	System	15 Sep 2020 00:36:07

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:35:56', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '67cb05c0-196e-4661-9f8b-ba8bb0547c85'	System	15 Sep 2020 00:36:07
User entered 'No (N)'	System	15 Sep 2020 00:36:07

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:35:57', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '67cb05c0-196e-4661-9f8b-ba8bb0547c85'	System	15 Sep 2020 00:36:07
User entered 'No (N)'	System	15 Sep 2020 00:36:07

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:35:59', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '67cb05c0-196e-4661-9f8b-ba8bb0547c85'	System	15 Sep 2020 00:36:07
User entered 'None (1)'	System	15 Sep 2020 00:36:07

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:36:03', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '67cb05c0-196e-4661-9f8b-ba8bb0547c85'	System	15 Sep 2020 00:36:07
User entered '14 Sep 2020 20:36'	System	15 Sep 2020 00:36:07

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:21:52', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'cc28d185-570a-4dd0-8f8f-d5b462577991'	System	08 Sep 2020 15:22:17
User entered 'None (0)'	System	08 Sep 2020 15:22:17

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:21:55', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'cc28d185-570a-4dd0-8f8f-d5b462577991'	System	08 Sep 2020 15:22:17
User entered 'None (0)'	System	08 Sep 2020 15:22:17

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:21:58', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'cc28d185-570a-4dd0-8f8f-d5b462577991'	System	08 Sep 2020 15:22:17
User entered 'None (0)'	System	08 Sep 2020 15:22:17

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:22:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'cc28d185-570a-4dd0-8f8f-d5b462577991'	System	08 Sep 2020 15:22:17
User entered 'None (0)'	System	08 Sep 2020 15:22:17

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:22:01', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'cc28d185-570a-4dd0-8f8f-d5b462577991'	System	08 Sep 2020 15:22:17
User entered 'None (0)'	System	08 Sep 2020 15:22:17

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:22:03', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'cc28d185-570a-4dd0-8f8f-d5b462577991'	System	08 Sep 2020 15:22:17
User entered 'None (0)'	System	08 Sep 2020 15:22:17

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:22:10', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'cc28d185-570a-4dd0-8f8f-d5b462577991'	System	08 Sep 2020 15:22:17
User entered 'No (N)'	System	08 Sep 2020 15:22:17

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T11:22:15', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'cc28d185-570a-4dd0-8f8f-d5b462577991'	System	08 Sep 2020 15:22:17
User entered '08 Sep 2020 11:22'	System	08 Sep 2020 15:22:17

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Sep 2020 11:21'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Sep 2020 13:51'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:26:17', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '33fb02d1-8de8-4c3f-ba80-e7811b03d199'	System	08 Sep 2020 23:28:59
User entered 'None (0)'	System	08 Sep 2020 23:28:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:26:20', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '33fb02d1-8de8-4c3f-ba80-e7811b03d199'	System	08 Sep 2020 23:28:59
User entered 'None (0)'	System	08 Sep 2020 23:28:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:26:45', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '33fb02d1-8de8-4c3f-ba80-e7811b03d199'	System	08 Sep 2020 23:28:59
User entered 'None (0)'	System	08 Sep 2020 23:28:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:28:45', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '33fb02d1-8de8-4c3f-ba80-e7811b03d199'	System	08 Sep 2020 23:28:59
User entered 'None (0)'	System	08 Sep 2020 23:28:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:27:13', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '33fb02d1-8de8-4c3f-ba80-e7811b03d199'	System	08 Sep 2020 23:28:59
User entered 'None (0)'	System	08 Sep 2020 23:28:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:27:16', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '33fb02d1-8de8-4c3f-ba80-e7811b03d199'	System	08 Sep 2020 23:28:59
User entered 'None (0)'	System	08 Sep 2020 23:28:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:27:30', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '33fb02d1-8de8-4c3f-ba80-e7811b03d199'	System	08 Sep 2020 23:28:59
User entered 'No (N)'	System	08 Sep 2020 23:28:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-08T19:28:57', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '33fb02d1-8de8-4c3f-ba80-e7811b03d199'	System	08 Sep 2020 23:28:59
User entered '08 Sep 2020 19:28'	System	08 Sep 2020 23:28:59

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '08 Sep 2020 14:46'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 2'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:28:57', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '88fafb4a-8c7d-4b1e-9712-b9c5793b3df8'	System	10 Sep 2020 02:29:35
User entered 'None (0)'	System	10 Sep 2020 02:29:35

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:28:59', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '88fafb4a-8c7d-4b1e-9712-b9c5793b3df8'	System	10 Sep 2020 02:29:35
User entered 'None (0)'	System	10 Sep 2020 02:29:35

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:29:01', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '88fafb4a-8c7d-4b1e-9712-b9c5793b3df8'	System	10 Sep 2020 02:29:35
User entered 'None (0)'	System	10 Sep 2020 02:29:35

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:29:17', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '88fafb4a-8c7d-4b1e-9712-b9c5793b3df8'	System	10 Sep 2020 02:29:35
User entered 'None (0)'	System	10 Sep 2020 02:29:35

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:29:20', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '88fafb4a-8c7d-4b1e-9712-b9c5793b3df8'	System	10 Sep 2020 02:29:35
User entered 'None (0)'	System	10 Sep 2020 02:29:35

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:29:22', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '88fafb4a-8c7d-4b1e-9712-b9c5793b3df8'	System	10 Sep 2020 02:29:35
User entered 'None (0)'	System	10 Sep 2020 02:29:35

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:29:24', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '88fafb4a-8c7d-4b1e-9712-b9c5793b3df8'	System	10 Sep 2020 02:29:35
User entered 'No (N)'	System	10 Sep 2020 02:29:35

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-09T22:29:29', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '88fafb4a-8c7d-4b1e-9712-b9c5793b3df8'	System	10 Sep 2020 02:29:35
User entered '09 Sep 2020 22:29'	System	10 Sep 2020 02:29:35

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 3'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:15:15', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '32235198-e20e-4c46-b1e8-5f6a77757295'	System	11 Sep 2020 01:15:53
User entered 'None (0)'	System	11 Sep 2020 01:15:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:15:20', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '32235198-e20e-4c46-b1e8-5f6a77757295'	System	11 Sep 2020 01:15:53
User entered 'None (0)'	System	11 Sep 2020 01:15:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:15:27', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '32235198-e20e-4c46-b1e8-5f6a77757295'	System	11 Sep 2020 01:15:53
User entered 'None (0)'	System	11 Sep 2020 01:15:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:15:38', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '32235198-e20e-4c46-b1e8-5f6a77757295'	System	11 Sep 2020 01:15:53
User entered 'None (0)'	System	11 Sep 2020 01:15:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:15:40', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '32235198-e20e-4c46-b1e8-5f6a77757295'	System	11 Sep 2020 01:15:53
User entered 'None (0)'	System	11 Sep 2020 01:15:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:15:42', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '32235198-e20e-4c46-b1e8-5f6a77757295'	System	11 Sep 2020 01:15:53
User entered 'None (0)'	System	11 Sep 2020 01:15:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:15:44', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '32235198-e20e-4c46-b1e8-5f6a77757295'	System	11 Sep 2020 01:15:53
User entered 'No (N)'	System	11 Sep 2020 01:15:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-10T21:15:49', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '32235198-e20e-4c46-b1e8-5f6a77757295'	System	11 Sep 2020 01:15:53
User entered '10 Sep 2020 21:15'	System	11 Sep 2020 01:15:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 4'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:35', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a6b42f8-87f5-4065-bda3-463661088a46'	System	11 Sep 2020 23:15:54
User entered 'None (0)'	System	11 Sep 2020 23:15:54

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:37', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a6b42f8-87f5-4065-bda3-463661088a46'	System	11 Sep 2020 23:15:54
User entered 'None (0)'	System	11 Sep 2020 23:15:54

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:38', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a6b42f8-87f5-4065-bda3-463661088a46'	System	11 Sep 2020 23:15:54
User entered 'None (0)'	System	11 Sep 2020 23:15:54

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:40', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a6b42f8-87f5-4065-bda3-463661088a46'	System	11 Sep 2020 23:15:54
User entered 'None (0)'	System	11 Sep 2020 23:15:54

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:42', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a6b42f8-87f5-4065-bda3-463661088a46'	System	11 Sep 2020 23:15:54
User entered 'None (0)'	System	11 Sep 2020 23:15:54

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:43', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a6b42f8-87f5-4065-bda3-463661088a46'	System	11 Sep 2020 23:15:54
User entered 'None (0)'	System	11 Sep 2020 23:15:54

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:46', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a6b42f8-87f5-4065-bda3-463661088a46'	System	11 Sep 2020 23:15:54
User entered 'No (N)'	System	11 Sep 2020 23:15:54

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-11T19:15:51', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2a6b42f8-87f5-4065-bda3-463661088a46'	System	11 Sep 2020 23:15:54
User entered '11 Sep 2020 19:15'	System	11 Sep 2020 23:15:54

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 5'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:43:54', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a02615e6-7b34-4366-b294-80906e7eb17b'	System	12 Sep 2020 23:44:11
User entered 'None (0)'	System	12 Sep 2020 23:44:11

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:43:51', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a02615e6-7b34-4366-b294-80906e7eb17b'	System	12 Sep 2020 23:44:11
User entered 'None (0)'	System	12 Sep 2020 23:44:11

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:43:44', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a02615e6-7b34-4366-b294-80906e7eb17b'	System	12 Sep 2020 23:44:11
User entered 'None (0)'	System	12 Sep 2020 23:44:11

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:43:42', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a02615e6-7b34-4366-b294-80906e7eb17b' User entered 'None (0)'	System	12 Sep 2020 23:44:11

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:43:41', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a02615e6-7b34-4366-b294-80906e7eb17b'	System	12 Sep 2020 23:44:11
User entered 'None (0)'	System	12 Sep 2020 23:44:11

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:43:56', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a02615e6-7b34-4366-b294-80906e7eb17b'	System	12 Sep 2020 23:44:11
User entered 'None (0)'	System	12 Sep 2020 23:44:11

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:44:02', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a02615e6-7b34-4366-b294-80906e7eb17b'	System	12 Sep 2020 23:44:11
User entered 'No (N)'	System	12 Sep 2020 23:44:11

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-12T19:44:08', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a02615e6-7b34-4366-b294-80906e7eb17b'	System	12 Sep 2020 23:44:11
User entered '12 Sep 2020 19:44'	System	12 Sep 2020 23:44:11

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 6'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:30:33', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '00af62e9-4e97-4dc5-b308-7d8125da11c8'	System	14 Sep 2020 12:30:49
User entered 'None (0)'	System	14 Sep 2020 12:30:49

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:30:35', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '00af62e9-4e97-4dc5-b308-7d8125da11c8'	System	14 Sep 2020 12:30:49
User entered 'None (0)'	System	14 Sep 2020 12:30:49

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:30:36', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '00af62e9-4e97-4dc5-b308-7d8125da11c8'	System	14 Sep 2020 12:30:49
User entered 'None (0)'	System	14 Sep 2020 12:30:49

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:30:37', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '00af62e9-4e97-4dc5-b308-7d8125da11c8'	System	14 Sep 2020 12:30:49
User entered 'None (0)'	System	14 Sep 2020 12:30:49

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:30:39', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '00af62e9-4e97-4dc5-b308-7d8125da11c8'	System	14 Sep 2020 12:30:49
User entered 'None (0)'	System	14 Sep 2020 12:30:49

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:30:40', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '00af62e9-4e97-4dc5-b308-7d8125da11c8'	System	14 Sep 2020 12:30:49
User entered 'None (0)'	System	14 Sep 2020 12:30:49

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:30:42', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '00af62e9-4e97-4dc5-b308-7d8125da11c8'	System	14 Sep 2020 12:30:49
User entered 'No (N)'	System	14 Sep 2020 12:30:49

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T08:30:46', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '00af62e9-4e97-4dc5-b308-7d8125da11c8'	System	14 Sep 2020 12:30:49
User entered '14 Sep 2020 08:30'	System	14 Sep 2020 12:30:49

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Sep 2020 15:06:00
User entered 'Day 7'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:35:31', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'effe459b-1575-4c33-89ed-8dd2b4746e2f'	System	15 Sep 2020 00:35:53
User entered 'None (0)'	System	15 Sep 2020 00:35:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:35:33', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'effe459b-1575-4c33-89ed-8dd2b4746e2f'	System	15 Sep 2020 00:35:53
User entered 'None (0)'	System	15 Sep 2020 00:35:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:35:36', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'effe459b-1575-4c33-89ed-8dd2b4746e2f'	System	15 Sep 2020 00:35:53
User entered 'None (0)'	System	15 Sep 2020 00:35:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:35:39', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'effe459b-1575-4c33-89ed-8dd2b4746e2f'	System	15 Sep 2020 00:35:53
User entered 'None (0)'	System	15 Sep 2020 00:35:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:35:40', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'effe459b-1575-4c33-89ed-8dd2b4746e2f'	System	15 Sep 2020 00:35:53
User entered 'None (0)'	System	15 Sep 2020 00:35:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:35:42', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'effe459b-1575-4c33-89ed-8dd2b4746e2f'	System	15 Sep 2020 00:35:53
User entered 'None (0)'	System	15 Sep 2020 00:35:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

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 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:35:44', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'effe459b-1575-4c33-89ed-8dd2b4746e2f'	System	15 Sep 2020 00:35:53
User entered 'No (N)'	System	15 Sep 2020 00:35:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-09-14T20:35:48', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'effe459b-1575-4c33-89ed-8dd2b4746e2f'	System	15 Sep 2020 00:35:53
User entered '14 Sep 2020 20:35'	System	15 Sep 2020 00:35:53

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 15:06:00

US3402288

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 15:06:00

US3402288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:20:31
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 21:10:15

US3402288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:20:31
User entered '16 Sep 2020'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 21:10:15

US3402288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:20:31
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 21:10:15

US3402288

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:20:31
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Sep 2020 21:10:15

US3402288

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:20:45
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 21:10:19

US3402288

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'I'	System	16 Sep 2020 21:10:19

US3402288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:20:55
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	22 Sep 2020 19:39:48

US3402288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:20:55
User entered '22 Sep 2020'	Traci Hull (b) (4) (b) (4)	22 Sep 2020 19:39:48

US3402288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:20:55
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	22 Sep 2020 19:39:48

US3402288

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:20:55
User entered empty.	Traci Hull (b) (4) (b) (4)	22 Sep 2020 19:39:48

US3402288

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:21:01
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	22 Sep 2020 19:39:38

US3402288

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered '1'	System	22 Sep 2020 19:39:38

US3402288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:21:16
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:57:45

US3402288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:21:16
User entered '29 Sep 2020'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:57:45

US3402288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:21:16
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:57:45

US3402288

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:21:16
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:57:45

US3402288

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:29:31
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:57:49

US3402288

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered 'I'	System	29 Sep 2020 19:57:49

US3402288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:31:28
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:27

US3402288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:31:28
User entered '7 Oct 2020'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:27

US3402288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:31:28
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:27

US3402288

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'VISIT3'	System	07 Oct 2020 14:44:27

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:21
User entered '7 Oct 2020'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:21
User entered '10:20'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered '7 Oct 2020 10:20'	System	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:21
User entered '36.7' C	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:21
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:21
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:21
User entered '95'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'bpm'	System	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:21
User entered '16'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'breaths/min'	System	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:21
User entered '126'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'mmHg'	System	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:21
User entered '86'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'mmHg'	System	07 Oct 2020 14:44:52

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18

US3402288

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18

US3402288

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:43
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:57

US3402288

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:43
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:57

US3402288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:50
User closed query 'Per GCL Lab Reconciliation: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 07OCT2020. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 12:35:30
Query 'Per GCL Lab Reconciliation: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 07OCT2020. Please clarify and update as appropriate.' answered with 'THE DATE IS CORRECT AS IS. THIS HAS ALREADY BEEN SENT BY OUR LAB TECH TO HAVE CORRECTED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	02 Nov 2020 13:09:02
User opened query 'Per GCL Lab Reconciliation: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 07OCT2020. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 23:04:10
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:45:09

US3402288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:50
User entered '7 Oct 2020'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:45:09

US3402288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:50
User entered '10:25'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:45:09

US3402288

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered '7 Oct 2020 10:25'	System	07 Oct 2020 14:45:09

US3402288

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:47:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:32:58
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 14:44:16

US3402288

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:18
User entered 'I'	System	07 Oct 2020 14:44:16

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 64'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-10-09T09:26:14', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7340f7d2-1dc9-4956-bfd2-b31056f08b32'	System	09 Oct 2020 13:26:34
User entered 'No (N)'	System	09 Oct 2020 13:26:34

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-10-09T09:26:21', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7340f7d2-1dc9-4956-bfd2-b31056f08b32'	System	09 Oct 2020 13:26:34
User entered 'No (N)'	System	09 Oct 2020 13:26:34

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-10-09T09:26:29', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7340f7d2-1dc9-4956-bfd2-b31056f08b32'	System	09 Oct 2020 13:26:34
User entered '09 Oct 2020 09:26:29'	System	09 Oct 2020 13:26:34

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 71'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-10-19T12:10:42', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'df51d9f0-a442-4c20-acd2-6409edd16bf1'	System	19 Oct 2020 16:10:55
User entered 'No (N)'	System	19 Oct 2020 16:10:55

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-10-19T12:10:48', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'df51d9f0-a442-4c20-acd2-6409edd16bf1'	System	19 Oct 2020 16:10:55
User entered 'No (N)'	System	19 Oct 2020 16:10:55

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-10-19T12:10:53', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'df51d9f0-a442-4c20-acd2-6409edd16bf1' User entered '19 Oct 2020 12:10:53'	System	19 Oct 2020 16:10:55
	System	19 Oct 2020 16:10:55

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 78'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-10-26T19:12:53', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2f3e0d2d-114c-4f8a-9bb2-abfedf9eb97c'	System	26 Oct 2020 23:13:16
User entered 'No (N)'	System	26 Oct 2020 23:13:16

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-10-26T19:13:07', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2f3e0d2d-114c-4f8a-9bb2-abfedf9eb97c'	System	26 Oct 2020 23:13:16
User entered 'No (N)'	System	26 Oct 2020 23:13:16

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-10-26T19:13:13', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2f3e0d2d-114c-4f8a-9bb2-abfedf9eb97c' User entered '26 Oct 2020 19:13:13'	System	26 Oct 2020 23:13:16
	System	26 Oct 2020 23:13:16

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 92'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-11-09T17:08:57', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4977fd1b-4db7-4e52-9574-dc194e61f727'	System	09 Nov 2020 22:09:27
User entered 'No (N)'	System	09 Nov 2020 22:09:27

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-11-09T17:09:13', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4977fd1b-4db7-4e52-9574-dc194e61f727'	System	09 Nov 2020 22:09:27
User entered 'No (N)'	System	09 Nov 2020 22:09:27

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d328d10105d7f795)', Time: '2020-11-09T17:09:18', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4977fd1b-4db7-4e52-9574-dc194e61f727'	System	09 Nov 2020 22:09:27
User entered '09 Nov 2020 17:09:18'	System	09 Nov 2020 22:09:27

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 99'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9cddb5dda62c107)', Time: '2020-11-16T15:00:14', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'f64c7105-b3e8-4eba-99cd-b26a67e5b7e6'	System	16 Nov 2020 20:00:28
User entered 'No (N)'	System	16 Nov 2020 20:00:28

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9cddb5dda62c107)', Time: '2020-11-16T15:00:23', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'f64c7105-b3e8-4eba-99cd-b26a67e5b7e6'	System	16 Nov 2020 20:00:28
User entered 'No (N)'	System	16 Nov 2020 20:00:28

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9cddb5dda62c107)', Time: '2020-11-16T15:00:26', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'f64c7105-b3e8-4eba-99cd-b26a67e5b7e6'	System	16 Nov 2020 20:00:28
User entered '16 Nov 2020 15:00:26'	System	16 Nov 2020 20:00:28

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:17:53
Data entry locked.	System	08 Aug 2020 14:27:59
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52
Data entry locked.	System	08 Aug 2020 14:27:59
User entered 'Day 106'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52
Data entry locked.	System	08 Aug 2020 14:27:59
User entered '19 Nov 2020 00:01'	System	08 Aug 2020 14:27:59

US3402288

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:29:52
Data entry locked.	System	08 Aug 2020 14:27:59
User entered '23 Nov 2020 23:59'	System	08 Aug 2020 14:27:59

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (e9cddb5dda62c107)', Time: '2020-11-23T15:44:29', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '189a8d3b-96cf-4aee-8d23-b0034d9cbf62'	System	23 Nov 2020 20:44:47
User entered 'No (N)'	System	23 Nov 2020 20:44:47

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (e9cddb5dda62c107)', Time: '2020-11-23T15:44:42', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '189a8d3b-96cf-4aee-8d23-b0034d9cbf62'	System	23 Nov 2020 20:44:47
User entered 'No (N)'	System	23 Nov 2020 20:44:47

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9cddb5dda62c107)', Time: '2020-11-23T15:44:45', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '189a8d3b-96cf-4aee-8d23-b0034d9cbf62'	System	23 Nov 2020 20:44:47
User entered '23 Nov 2020 15:44:45'	System	23 Nov 2020 20:44:47

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (e9cddb5dda62c107)', Time: '2020-11-30T11:36:28', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '27f9c4df-edbc-434d-926a-8cd84f34a605'	System	30 Nov 2020 16:36:39
User entered 'No (N)'	System	30 Nov 2020 16:36:39

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Have you been exposed to someone with 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 (e9cddb5dda62c107)', Time: '2020-11-30T11:36:32', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '27f9c4df-edbc-434d-926a-8cd84f34a605'	System	30 Nov 2020 16:36:39
User entered 'No (N)'	System	30 Nov 2020 16:36:39

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9cddb5dda62c107)', Time: '2020-11-30T11:36:35', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '27f9c4df-edbc-434d-926a-8cd84f34a605'	System	30 Nov 2020 16:36:39
User entered '30 Nov 2020 11:36:35'	System	30 Nov 2020 16:36:39

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (e9cddb5dda62c107)', Time: '2020-12-09T23:59:31', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a7e7ff03-bb79-4baa-adee-2f4755273ea3'	System	10 Dec 2020 04:59:56
User entered 'No (N)'	System	10 Dec 2020 04:59:56

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (e9cddb5dda62c107)', Time: '2020-12-09T23:59:44', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a7e7ff03-bb79-4baa-adee-2f4755273ea3'	System	10 Dec 2020 04:59:56
User entered 'No (N)'	System	10 Dec 2020 04:59:56

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9cddb5dda62c107)', Time: '2020-12-09T23:59:51', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a7e7ff03-bb79-4baa-adee-2f4755273ea3' User entered '09 Dec 2020 23:59:51'	System	10 Dec 2020 04:59:56
	System	10 Dec 2020 04:59:56

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	Melita Rebello (2403 - melita_r2)	10 Mar 2021 05:24:56
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'AE WAS ADDED FOR ABSESSED TOOTH. ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	09 Mar 2021 18:55:57
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	Ann Marie Claire Remolar (2695 - remolaam1)	01 Mar 2021 14:28:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9cddb5dda62c107)', Time: '2020-12-16T11:23:50', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '83d2ba39-db8d-4d3b-a5ab-7713c21e7ef2'	System	16 Dec 2020 16:28:43
User entered 'Yes (Y)'	System	16 Dec 2020 16:28:43

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Have you been exposed to someone with 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 (e9cddb5dda62c107)', Time: '2020-12-16T11:24:09', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '83d2ba39-db8d-4d3b-a5ab-7713c21e7ef2'	System	16 Dec 2020 16:28:43
User entered 'No (N)'	System	16 Dec 2020 16:28:43

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (e9cddb5dda62c107)', Time: '2020-12-16T11:24:12', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '83d2ba39-db8d-4d3b-a5ab-7713c21e7ef2'	System	16 Dec 2020 16:28:43
User entered 'No (N)'	System	16 Dec 2020 16:28:43

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (e9cddb5dda62c107)', Time: '2020-12-16T11:24:49', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '83d2ba39-db8d-4d3b-a5ab-7713c21e7ef2'	System	16 Dec 2020 16:28:43
User entered 'Yes (Y)'	System	16 Dec 2020 16:28:43

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Please 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 (e9cddb5dda62c107)', Time: '2020-12-16T11:24:56', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '83d2ba39-db8d-4d3b-a5ab-7713c21e7ef2'	System	16 Dec 2020 16:28:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 16:28:43

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9cddb5dda62c107)', Time: '2020-12-16T11:28:31', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '83d2ba39-db8d-4d3b-a5ab-7713c21e7ef2' User entered '16 Dec 2020 11:28:31'	System	16 Dec 2020 16:28:43
	System	16 Dec 2020 16:28:43

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (e9cddb5dda62c107)', Time: '2020-12-23T20:54:11', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '31553db4-b2fc-4de1-aafd-589bb4658dab' User entered 'No (N)'	System	24 Dec 2020 01:54:20

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (e9cddb5dda62c107)', Time: '2020-12-23T20:54:12', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '31553db4-b2fc-4de1-aafd-589bb4658dab' User entered 'No (N)'	System	24 Dec 2020 01:54:20

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e9cddb5dda62c107)', Time: '2020-12-23T20:54:17', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '31553db4-b2fc-4de1-aafd-589bb4658dab' User entered '23 Dec 2020 20:54:17'	System	24 Dec 2020 01:54:20

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (611936ae8a416547)', Time: '2020-12-31T14:22:12', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '804b0c0d-0cd7-47cc-8b4f-4c1e34214177'	System	31 Dec 2020 19:22:28
User entered 'No (N)'	System	31 Dec 2020 19:22:28

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Have you been exposed to someone with 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 (611936ae8a416547)', Time: '2020-12-31T14:22:21', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '804b0c0d-0cd7-47cc-8b4f-4c1e34214177'	System	31 Dec 2020 19:22:28
User entered 'No (N)'	System	31 Dec 2020 19:22:28

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2020-12-31T14:22:26', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '804b0c0d-0cd7-47cc-8b4f-4c1e34214177'	System	31 Dec 2020 19:22:28
User entered '31 Dec 2020 14:22:26'	System	31 Dec 2020 19:22:28

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (611936ae8a416547)', Time: '2021-01-06T10:43:34', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '28cb98d1-148d-45ac-a8a3-5a6468fe8a87'	System	06 Jan 2021 15:43:42
User entered 'No (N)'	System	06 Jan 2021 15:43:42

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Have you been exposed to someone with 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 (611936ae8a416547)', Time: '2021-01-06T10:43:36', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '28cb98d1-148d-45ac-a8a3-5a6468fe8a87'	System	06 Jan 2021 15:43:42
User entered 'No (N)'	System	06 Jan 2021 15:43:42

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-01-06T10:43:41', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '28cb98d1-148d-45ac-a8a3-5a6468fe8a87'	System	06 Jan 2021 15:43:42
User entered '06 Jan 2021 10:43:41'	System	06 Jan 2021 15:43:42

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (611936ae8a416547)', Time: '2021-01-13T12:32:51', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '927ae54c-3e6f-46d1-a145-7d953bf40ac2'	System	13 Jan 2021 17:33:02
User entered 'No (N)'	System	13 Jan 2021 17:33:02

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Have you been exposed to someone with 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 (611936ae8a416547)', Time: '2021-01-13T12:32:54', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '927ae54c-3e6f-46d1-a145-7d953bf40ac2'	System	13 Jan 2021 17:33:02
User entered 'No (N)'	System	13 Jan 2021 17:33:02

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-01-13T12:32:59', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '927ae54c-3e6f-46d1-a145-7d953bf40ac2'	System	13 Jan 2021 17:33:02
User entered '13 Jan 2021 12:32:59'	System	13 Jan 2021 17:33:02

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (611936ae8a416547)', Time: '2021-01-20T16:12:28', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '5167b9fe-e969-467d-833e-01203906e86a'	System	20 Jan 2021 21:12:37
User entered 'No (N)'	System	20 Jan 2021 21:12:37

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Have you been exposed to someone with 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 (611936ae8a416547)', Time: '2021-01-20T16:12:31', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '5167b9fe-e969-467d-833e-01203906e86a'	System	20 Jan 2021 21:12:37
User entered 'No (N)'	System	20 Jan 2021 21:12:37

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-01-20T16:12:34', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '5167b9fe-e969-467d-833e-01203906e86a' User entered '20 Jan 2021 16:12:34'	System	20 Jan 2021 21:12:37
	System	20 Jan 2021 21:12:37

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (611936ae8a416547)', Time: '2021-01-27T12:45:22', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'b51d51d6-53cb-4a54-aa49-6a8300a381c6'	System	27 Jan 2021 17:45:31
User entered 'No (N)'	System	27 Jan 2021 17:45:31

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (611936ae8a416547)', Time: '2021-01-27T12:45:24', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'b51d51d6-53cb-4a54-aa49-6a8300a381c6'	System	27 Jan 2021 17:45:31
User entered 'No (N)'	System	27 Jan 2021 17:45:31

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-01-27T12:45:27', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'b51d51d6-53cb-4a54-aa49-6a8300a381c6' User entered '27 Jan 2021 12:45:27'	System	27 Jan 2021 17:45:31

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (611936ae8a416547)', Time: '2021-02-04T13:12:47', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '72ee43ad-9390-46f7-b3e2-b023dc353549'	System	04 Feb 2021 18:13:29
User entered 'No (N)'	System	04 Feb 2021 18:13:29

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Have you been exposed to someone with 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 (611936ae8a416547)', Time: '2021-02-04T13:12:59', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '72ee43ad-9390-46f7-b3e2-b023dc353549'	System	04 Feb 2021 18:13:29
User entered 'No (N)'	System	04 Feb 2021 18:13:29

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-02-04T13:13:03', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '72ee43ad-9390-46f7-b3e2-b023dc353549'	System	04 Feb 2021 18:13:29
User entered '04 Feb 2021 13:13:03'	System	04 Feb 2021 18:13:29

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (611936ae8a416547)', Time: '2021-02-10T13:58:40', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ce71f99a-4a61-4d2c-b107-4529c41c196e'	System	10 Feb 2021 18:58:51
User entered 'No (N)'	System	10 Feb 2021 18:58:51

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (611936ae8a416547)', Time: '2021-02-10T13:58:46', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ce71f99a-4a61-4d2c-b107-4529c41c196e'	System	10 Feb 2021 18:58:51
User entered 'No (N)'	System	10 Feb 2021 18:58:51

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-02-10T13:58:49', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ce71f99a-4a61-4d2c-b107-4529c41c196e'	System	10 Feb 2021 18:58:51
User entered '10 Feb 2021 13:58:49'	System	10 Feb 2021 18:58:51

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (611936ae8a416547)', Time: '2021-02-17T09:57:45', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7eb4b944-0276-44ca-b6bf-29f645530d9e'	System	17 Feb 2021 14:57:54
User entered 'No (N)'	System	17 Feb 2021 14:57:54

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (611936ae8a416547)', Time: '2021-02-17T09:57:48', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7eb4b944-0276-44ca-b6bf-29f645530d9e'	System	17 Feb 2021 14:57:54
User entered 'No (N)'	System	17 Feb 2021 14:57:54

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-02-17T09:57:50', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '7eb4b944-0276-44ca-b6bf-29f645530d9e'	System	17 Feb 2021 14:57:54
User entered '17 Feb 2021 09:57:50'	System	17 Feb 2021 14:57:54

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (611936ae8a416547)', Time: '2021-02-24T16:19:58-05:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '19770148-89be-46ae-9ef9-8c4feb34a83d' User entered 'No (N)'	System	24 Feb 2021 21:20:16
	System	24 Feb 2021 21:20:16

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (611936ae8a416547)', Time: '2021-02-24T16:20:07-05:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '19770148-89be-46ae-9ef9-8c4feb34a83d' User entered 'No (N)'	System	24 Feb 2021 21:20:16

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-02-24T16:20:11-05:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '19770148-89be-46ae-9ef9-8c4feb34a83d' User entered '24 Feb 2021 16:20:11'	System	24 Feb 2021 21:20:16
	System	24 Feb 2021 21:20:16

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (611936ae8a416547)', Time: '2021-03-03T09:38:24-05:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '177b00d9-d4aa-4b6a-8ba6-3782fb0d2a1e'	System	03 Mar 2021 14:38:32
User entered 'No (N)'	System	03 Mar 2021 14:38:32

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (611936ae8a416547)', Time: '2021-03-03T09:38:26-05:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '177b00d9-d4aa-4b6a-8ba6-3782fb0d2a1e'	System	03 Mar 2021 14:38:32
User entered 'No (N)'	System	03 Mar 2021 14:38:32

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-03-03T09:38:29-05:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '177b00d9-d4aa-4b6a-8ba6-3782fb0d2a1e' User entered '03 Mar 2021 09:38:29'	System	03 Mar 2021 14:38:32
	System	03 Mar 2021 14:38:32

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (611936ae8a416547)', Time: '2021-03-10T11:02:19-05:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4e77ef18-75ac-4fbc-82ae-594bf6542bb3'	System	10 Mar 2021 16:02:38
User entered 'No (N)'	System	10 Mar 2021 16:02:38

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (611936ae8a416547)', Time: '2021-03-10T11:02:30-05:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4e77ef18-75ac-4fbc-82ae-594bf6542bb3'	System	10 Mar 2021 16:02:38
User entered 'No (N)'	System	10 Mar 2021 16:02:38

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-03-10T11:02:33-05:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '4e77ef18-75ac-4fbc-82ae-594bf6542bb3' User entered '10 Mar 2021 11:02:33'	System	10 Mar 2021 16:02:38

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (611936ae8a416547)', Time: '2021-03-17T12:43:19-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c6530dbe-c640-4e83-a3a0-b2196e8683e3'	System	17 Mar 2021 16:43:34
User entered 'No (N)'	System	17 Mar 2021 16:43:34

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (611936ae8a416547)', Time: '2021-03-17T12:43:27-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c6530dbe-c640-4e83-a3a0-b2196e8683e3'	System	17 Mar 2021 16:43:34
User entered 'No (N)'	System	17 Mar 2021 16:43:34

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-03-17T12:43:31-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'c6530dbe-c640-4e83-a3a0-b2196e8683e3' User entered '17 Mar 2021 12:43:31'	System	17 Mar 2021 16:43:34
	System	17 Mar 2021 16:43:34

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-03-24T10:43:06-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '1ee0e33b-bfa4-4b58-be42-40f47586bf2e'	System	24 Mar 2021 14:43:20
User entered 'No (N)'	System	24 Mar 2021 14:43:20

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-03-24T10:43:11-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '1ee0e33b-bfa4-4b58-be42-40f47586bf2e'	System	24 Mar 2021 14:43:20
User entered 'No (N)'	System	24 Mar 2021 14:43:20

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-03-24T10:43:17-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '1ee0e33b-bfa4-4b58-be42-40f47586bf2e' User entered '24 Mar 2021 10:43:17'	System	24 Mar 2021 14:43:20
	System	24 Mar 2021 14:43:20

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-03-31T16:46:22-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'e9e2d15e-395d-4ffe-af0e-9286cfb2003a' User entered 'No (N)'	System	31 Mar 2021 20:46:42
	System	31 Mar 2021 20:46:42

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-03-31T16:46:25-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'e9e2d15e-395d-4ffe-af0e-9286cfb2003a' User entered 'No (N)'	System	31 Mar 2021 20:46:42

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-03-31T16:46:29-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'e9e2d15e-395d-4ffe-af0e-9286cfb2003a' User entered '31 Mar 2021 16:46:29'	System	31 Mar 2021 20:46:42
	System	31 Mar 2021 20:46:42

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-08T08:12:17-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ce4db7e6-e0bc-43b2-b682-bf03421b1a88'	System	08 Apr 2021 12:12:48
User entered 'Yes (Y)'	System	08 Apr 2021 12:12:48

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-08T08:12:10-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ce4db7e6-e0bc-43b2-b682-bf03421b1a88'	System	08 Apr 2021 12:12:48
User entered 'No (N)'	System	08 Apr 2021 12:12:48

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-08T08:12:08-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ce4db7e6-e0bc-43b2-b682-bf03421b1a88'	System	08 Apr 2021 12:12:48
User entered 'No (N)'	System	08 Apr 2021 12:12:48

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-08T08:12:27-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ce4db7e6-e0bc-43b2-b682-bf03421b1a88'	System	08 Apr 2021 12:12:48
User entered 'No (N)'	System	08 Apr 2021 12:12:48

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-08T08:12:44-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'ce4db7e6-e0bc-43b2-b682-bf03421b1a88' User entered '08 Apr 2021 08:12:44'	System	08 Apr 2021 12:12:48
	System	08 Apr 2021 12:12:48

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-14T14:32:51-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a3ef3213-4289-4ba8-a508-df831496f11d'	System	19 Apr 2021 00:12:43
User entered 'No (N)'	System	19 Apr 2021 00:12:43

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-14T14:32:58-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a3ef3213-4289-4ba8-a508-df831496f11d'	System	19 Apr 2021 00:12:43
User entered 'No (N)'	System	19 Apr 2021 00:12:43

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-14T14:33:01-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: 'a3ef3213-4289-4ba8-a508-df831496f11d'	System	19 Apr 2021 00:12:43
User entered '14 Apr 2021 14:33:01'	System	19 Apr 2021 00:12:43

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-21T09:22:02-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '046aebc8-c09b-4135-a4c1-aa4f59c4f5a5' User entered 'No (N)'	System	21 Apr 2021 13:22:14
	System	21 Apr 2021 13:22:14

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

Have you been exposed to someone with 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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-21T09:22:04-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '046aebc8-c09b-4135-a4c1-aa4f59c4f5a5'	System	21 Apr 2021 13:22:14
User entered 'No (N)'	System	21 Apr 2021 13:22:14

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-21T09:22:07-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '046aebc8-c09b-4135-a4c1-aa4f59c4f5a5'	System	21 Apr 2021 13:22:14
User entered '21 Apr 2021 09:22:07'	System	21 Apr 2021 13:22:14

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-28T09:32:10-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2919e11f-a6b9-48ab-818d-649373ff7ebc'	System	29 Apr 2021 00:41:44
User entered 'No (N)'	System	29 Apr 2021 00:41:44

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Have you been exposed to someone with 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 (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-28T09:32:15-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2919e11f-a6b9-48ab-818d-649373ff7ebc'	System	29 Apr 2021 00:41:44
User entered 'No (N)'	System	29 Apr 2021 00:41:44

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8846D2C9-CAC0-4D85-918B-F16E703CB2F2)', Time: '2021-04-28T09:32:18-04:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '2919e11f-a6b9-48ab-818d-649373ff7ebc'	System	29 Apr 2021 00:41:44
User entered '28 Apr 2021 09:32:18'	System	29 Apr 2021 00:41:44

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:29:52

US3402288

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:29:52
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:29:52

US3402288

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:26:32

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)	26 Apr 2021 06:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-03-03T09:38:16-05:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '27b44b4b-47da-4f8f-9412-db4dd8af4dc9'	System	03 Mar 2021 14:38:24
User entered 'No (N)'	System	03 Mar 2021 14:38:24

US3402288

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:26:32

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (611936ae8a416547)', Time: '2021-03-03T09:38:20-05:00', User OID: 'PatientReportedOutcome (US3402288)', ODM File OID: '27b44b4b-47da-4f8f-9412-db4dd8af4dc9' User entered '03 Mar 2021 09:38:20'	System	03 Mar 2021 14:38:24
	System	03 Mar 2021 14:38:24

US3402288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:24:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:34:33
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	02 Nov 2020 17:02:37

US3402288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:24:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:34:33
User entered '2 Nov 2020'	Tammy Kohn (b) (4) (b) (4)	02 Nov 2020 17:02:37

US3402288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:24:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:34:33
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	02 Nov 2020 17:02:37

US3402288

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:24:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:34:33
User entered empty.	Tammy Kohn (b) (4) (b) (4)	02 Nov 2020 17:02:37

US3402288

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:24:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:34:48
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	02 Nov 2020 17:02:40

US3402288

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:02:08
User entered '1'	System	02 Nov 2020 17:02:40

US3402288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:47:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 20:45:20

US3402288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:47:48
User entered '4 Dec 2020'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 20:45:20

US3402288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:47:48
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 20:45:20

US3402288

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:47:48
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Dec 2020 20:45:20

US3402288

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:47:53
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	04 Dec 2020 20:45:30

US3402288

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User entered 'I'	System	04 Dec 2020 20:45:30

US3402288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:48:16
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	06 Jan 2021 20:56:36

US3402288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:48:16
User entered '6 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	06 Jan 2021 20:56:36

US3402288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:48:16
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	06 Jan 2021 20:56:36

US3402288

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:48:16
User entered empty.	Tammy Kohn (b) (4) (b) (4)	06 Jan 2021 20:56:36

US3402288

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:48:20
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	06 Jan 2021 20:56:40

US3402288

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User entered 'I'	System	06 Jan 2021 20:56:40

US3402288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:56:27
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 14:54:39

US3402288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:56:27
User entered '3 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 14:54:39

US3402288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:56:27
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 14:54:39

US3402288

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:56:27
User entered empty.	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 14:54:39

US3402288

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:56:36
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 14:54:42

US3402288

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:34:49
User entered 'I'	System	04 Feb 2021 14:54:42

US3402288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:25
User closed query 'Per CDM: Please complete Vital signs page under Visit 4 folder. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:43:03
Query 'Per CDM: Please complete Vital signs page under Visit 4 folder. Thank you' answered with 'VITALS WERE NOT TAKEN AT VISIT 4' (Site from DM).	Traci Hull (b) (4) (b) (4)	31 Mar 2021 12:48:36
User opened query 'Per CDM: Please complete Vital signs page under Visit 4 folder. Thank you' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 04:36:59
Query 'Per CDM' Please complete Vital signs page under Visit 4 folder. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 04:36:36
User opened query 'Per CDM' Please complete Vital signs page under Visit 4 folder. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 04:36:26
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:20:48

US3402288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:25
User entered '3 Mar 2021'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:20:48

US3402288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:25
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:20:48

US3402288

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User entered 'VISIT4'	System	03 Mar 2021 20:20:48

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:31
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:31
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:31
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User entered empty.	System	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:31
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:31
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:31
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:31
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User entered empty.	System	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:31
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User entered empty.	System	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:31
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User entered empty.	System	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:31
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User entered empty.	System	31 Mar 2021 12:33:01

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23

US3402288

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23

US3402288

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:43
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:21:11

US3402288

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:43
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:21:11

US3402288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:51
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:21:48

US3402288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:51
User entered '3 Mar 2021'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:21:48

US3402288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:51
User entered '14:15'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:21:48

US3402288

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User entered '3 Mar 2021 14:15'	System	03 Mar 2021 20:21:48

US3402288

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 02:38:35
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:21:58

US3402288

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:23
User entered 'I'	System	03 Mar 2021 20:21:58

US3402288

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Apr 2021 19:26:59
	(b) (4)	

US3402288

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
User entered '5 Apr 2021'	Tammy Kohn (b) (4)	05 Apr 2021 19:26:59
	(b) (4)	

US3402288

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	05 Apr 2021 19:26:59
	(b) (4)	

US3402288

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	05 Apr 2021 19:26:59
	(b) (4)	

US3402288

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Apr 2021 19:27:02
	(b) (4)	

US3402288

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:27:02

US3402288

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

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:48:56
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:08:21

US3402288

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

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:48:56
	(b) (4), (b) (6)	
User entered '07 Jan 2021'	Traci Hull (b) (4)	07 Jan 2021 17:08:21
	(b) (4)	

US3402288

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

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:48:56
	(b) (4), (b) (6)	
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	07 Jan 2021 17:08:21
	(b) (4)	

US3402288

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

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered 'UNBLND_DECIDE'	System	07 Jan 2021 17:08:21

US3402288

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:32

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:11
User closed query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:51:47
Query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	08 Apr 2021 13:48:47
User entered '06 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	08 Apr 2021 13:48:40
User opened query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 19:29:38
User entered '24 Dec 2020'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:09:30

US3402288

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:11
User entered '0'	Traci Hull (b) (4)	08 Apr 2021 13:48:40
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:58:26

US3402288

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:32

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:11
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	07 Jan 2021 17:09:30
	(b) (4)	

US3402288

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:32

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:11
User entered 'Amendment 6 or later (Amendment 6 or later)'	Traci Hull (b) (4)	08 Apr 2021 13:48:40
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:58:26

US3402288

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:32

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:11
	(b) (4), (b) (6)	
User entered '07 Jan 2021'	Traci Hull (b) (4)	07 Jan 2021 17:09:30
	(b) (4)	

US3402288

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:32

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:11
	(b) (4), (b) (6)	
User entered 'Placebo (Placebo)'	Traci Hull (b) (4)	07 Jan 2021 17:09:30
	(b) (4)	

US3402288

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:32

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:11
	(b) (4), (b) (6)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:45:54
User entered 'Placebo (Placebo)'	Traci Hull (b) (4)	07 Jan 2021 17:09:30
	(b) (4)	

US3402288

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:32

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:11
	(b) (4), (b) (6)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:45:54
User entered 'Placebo (Placebo)'	Traci Hull (b) (4)	07 Jan 2021 17:09:30
	(b) (4)	

US3402288

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:32

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:11
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:09:30

US3402288

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:32

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered '1'	System	07 Jan 2021 17:09:30

US3402288

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:32

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered 'I'	System	07 Jan 2021 17:09:30

US3402288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:53
	(b) (4), (b) (6)	
User entered missing code ND - Not Done.	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered empty.	System	07 Jan 2021 17:13:16
DataPoint set to visible.	System	07 Jan 2021 17:09:30

US3402288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered missing code ND - Not Done.	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:53
	(b) (4), (b) (6)	
User entered missing code ND - Not Done.	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered empty.	System	07 Jan 2021 17:13:16
DataPoint set to visible.	System	07 Jan 2021 17:09:30

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered '07 Jan 2021'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered '10:51'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered '07 Jan 2021 10:51'	System	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:53
	(b) (4), (b) (6)	
User entered '36.0' C	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:53
	(b) (4), (b) (6)	
User entered 'Oral (Oral)'	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:53
	(b) (4), (b) (6)	
User entered empty.	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:53
	(b) (4), (b) (6)	
User entered '76'	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered 'bpm'	System	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:53
	(b) (4), (b) (6)	
User entered '14'	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered 'breaths/min'	System	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered '126'	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered 'mmHg'	System	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered '80'	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered 'mmHg'	System	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:53
	(b) (4), (b) (6)	
User entered missing code ND - Not Done.	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered empty.	System	07 Jan 2021 17:13:16
DataPoint set to visible.	System	07 Jan 2021 17:09:30

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered '07 Jan 2021'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered '11:55'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered '07 Jan 2021 11:55'	System	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:53
	(b) (4), (b) (6)	
User entered '36.2' C	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:53
	(b) (4), (b) (6)	
User entered 'Oral (Oral)'	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered '74'	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered 'bpm'	System	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	13 Apr 2021 16:49:53
	(b) (4), (b) (6)	
User entered '14'	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered 'breaths/min'	System	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered '120'	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered 'mmHg'	System	07 Jan 2021 17:13:16

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:49:53
User entered '78'	Traci Hull (b) (4)	07 Jan 2021 17:13:16
	(b) (4)	

US3402288

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered 'mmHg'	System	07 Jan 2021 17:13:16

US3402288

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	13 Apr 2021 16:50:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	07 Jan 2021 17:13:55
	(b) (4)	

US3402288

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	13 Apr 2021 16:50:02
	(b) (4), (b) (6)	
User entered '07 Jan 2021'	Traci Hull (b) (4)	07 Jan 2021 17:13:55
	(b) (4)	

US3402288

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

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	12 Apr 2021 19:04:28
User entered 'Yes (Y)'	Traci Hull (b) (4)	07 Jan 2021 17:14:16

US3402288

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

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	12 Apr 2021 19:04:28
User entered empty.	Traci Hull (b) (4)	07 Jan 2021 17:14:16

US3402288

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

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:04:28
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:14:16

US3402288

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

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered 'mRNA-1273'	System	07 Jan 2021 17:14:16
DataPoint set to visible.	System	07 Jan 2021 17:09:30

US3402288

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

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	12 Apr 2021 19:04:28
User entered '07 Jan 2021'	Traci Hull (b) (4)	07 Jan 2021 17:14:16

US3402288

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

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:04:28
User entered '11:23'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:14:16

US3402288

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

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered '07 Jan 2021 11:23'	System	07 Jan 2021 17:14:16

US3402288

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

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:04:28
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4)	07 Jan 2021 17:14:16
	(b) (4)	

US3402288

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

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:28
User entered 'ONCE'	System	07 Jan 2021 17:14:16

US3402288

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

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered 'INTRAMUSCULAR'	System	07 Jan 2021 17:14:16

US3402288

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:51:53
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:08:46

US3402288

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:51:53
User entered '07 Jan 2021'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:08:46

US3402288

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	13 Apr 2021 16:51:53
	(b) (4), (b) (6)	
User entered '10:43'	Traci Hull (b) (4)	07 Jan 2021 17:08:46
	(b) (4)	

US3402288

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered '07 Jan 2021 10:43'	System	07 Jan 2021 17:08:46

US3402288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:51:56
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:09:05

US3402288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:51:56
User entered '07 Jan 2021'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:09:05

US3402288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:51:56
User entered '10:45'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 17:09:05

US3402288

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:32

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered '07 Jan 2021 10:45'	System	07 Jan 2021 17:09:05

US3402288

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

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	13 Apr 2021 16:52:03
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	07 Jan 2021 17:17:53
	(b) (4)	

US3402288

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

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:24:29
User entered '1'	System	07 Jan 2021 17:17:53

US3402288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:53:45
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 20:54:48

US3402288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:53:45
User entered '14 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 20:54:48

US3402288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:53:45
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 20:54:48

US3402288

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:53:45
User entered empty.	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 20:54:48

US3402288

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:17
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:54:01
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	14 Jan 2021 20:54:52

US3402288

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:17
User entered '1'	System	14 Jan 2021 20:54:52

US3402288

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:17
User entered '1'	System	14 Jan 2021 20:54:52
DataPoint set to visible.	System	14 Jan 2021 20:54:52

US3402288

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:54:50
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:44:39

US3402288

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:54:50
User entered '5 Feb 2021'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:44:39

US3402288

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:54:50
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:44:39

US3402288

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered 'OLD29'	System	05 Feb 2021 17:44:39

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '5 Feb 2021'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '11:10'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered '5 Feb 2021 11:10'	System	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '37.1' C	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '62'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered 'bpm'	System	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '20'	Traci Hull (b) (4)	05 Feb 2021 17:47:36
	(b) (4)	

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered 'breaths/min'	System	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '130'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered 'mmHg'	System	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '80'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered 'mmHg'	System	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '5 Feb 2021'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '12:11'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered '5 Feb 2021 12:11'	System	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	13 Apr 2021 16:55:22
	(b) (4), (b) (6)	
User entered '36.3' C	Traci Hull (b) (4)	05 Feb 2021 17:47:36
	(b) (4)	

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '80'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered 'bpm'	System	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '18'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered 'breaths/min'	System	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '138'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered 'mmHg'	System	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:22
User entered '68'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered 'mmHg'	System	05 Feb 2021 17:47:36

US3402288

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:36
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:42

US3402288

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:36
User entered '5 Feb 2021'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:47:42

US3402288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	Traci Hull (b) (4)	05 Feb 2021 17:48:03
	(b) (4)	

US3402288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Traci Hull (b) (4)	05 Feb 2021 17:48:03
	(b) (4)	

US3402288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:29:08
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:48:03

US3402288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered 'mRNA-1273'	System	05 Feb 2021 17:48:03
DataPoint set to visible.	System	14 Jan 2021 20:54:52

US3402288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '5 Feb 2021'	Traci Hull (b) (4)	05 Feb 2021 17:48:03
	(b) (4)	

US3402288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:29:08
User entered '11:40'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:48:03

US3402288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered '5 Feb 2021 11:40'	System	05 Feb 2021 17:48:03

US3402288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:29:08
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:48:03

US3402288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:29:08
User entered 'ONCE'	System	05 Feb 2021 17:48:03

US3402288

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 17:48:03

US3402288

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:55:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 17:48:08

US3402288

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:37
User entered 'I'	System	05 Feb 2021 17:48:08

US3402288

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:57:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:56:55
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 15:24:27

US3402288

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:57:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:56:55
User entered '12 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 15:24:27

US3402288

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:57:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:56:55
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 15:24:27

US3402288

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:57:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:56:55
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 15:24:27

US3402288

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:57:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:57:00
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 15:24:32

US3402288

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:57:38
User entered 'I'	System	16 Feb 2021 15:24:32

US3402288

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:17
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:12

US3402288

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:17
User entered '3 Mar 2021'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:12

US3402288

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:17
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:12

US3402288

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User entered 'OLD57'	System	03 Mar 2021 20:19:12

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:23
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:23
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:23
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User entered empty.	System	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:23
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:23
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:23
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:23
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User entered empty.	System	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:23
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User entered empty.	System	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:23
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User entered empty.	System	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:23
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User entered empty.	System	03 Mar 2021 20:19:46

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51

US3402288

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51

US3402288

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:30
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:20:02

US3402288

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:30
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:20:02

US3402288

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:37
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:20:14

US3402288

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:37
User entered '3 Mar 2021'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:20:14

US3402288

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:58:37
User entered '14:15'	Tammy Kohn (b) (4) (b) (4)	03 Mar 2021 20:20:14

US3402288

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:51
User entered '3 Mar 2021 14:15'	System	03 Mar 2021 20:20:14

US3402288

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:26:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:35:49
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
DataPoint Un-verified.	Tammy Kohn (b) (4)	05 Jan 2021 20:12:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Jan 2021 20:12:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 20:04:37
User entered 'No (N)'	Traci Hull (b) (4)	04 Sep 2020 15:18:21

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth abscess, LLT: Tooth abscess - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 20:15:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 20:15:31
Data point term sent to Coder	System	05 Jan 2021 20:14:44
User entered 'ABCESS TOOTH'	Tammy Kohn (b) (4) (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered 'No (N)'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered 'No (N)'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered '21 Dec 2020'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered empty.	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
User entered empty.	System	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered 'No (N)'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered '29 Dec 2020'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered empty.	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
User entered empty.	System	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered 'No (N)'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered '0'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered '0'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered '0'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered empty.	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered empty.	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered empty.	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered empty.	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered '0'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered '0'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered '0'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered 'Not Related (NOT RELATED)'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered 'Not Related (NOT RELATED)'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered 'Not Applicable (NOT APPLICABLE)'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered '0'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered 'l'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered '0'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered empty.	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:47:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:01
User entered empty.	Tammy Kohn (b) (4)	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
User entered '0'	System	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03
User entered '1'	System	05 Jan 2021 20:14:02

US3402288

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:03

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 19:11:13
User entered	System	21 Apr 2021 19:10:57
'USA-US059-2021-mRNA-1273-P301000015'		
User entered 'New'	(b) (4), (b) (6)	21 Apr 2021 19:10:57

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia, LLT: Abdominal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 13:54:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 13:54:15
Data point term sent to Coder	System	21 Apr 2021 13:49:52
User entered 'Abdominal Hernia'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	21 Apr 2021 13:49:43

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	21 Apr 2021 13:49:43

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered '02 Apr 2021'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered empty.	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 13:49:43

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'No (N)'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered '11 Apr 2021'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered empty.	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 13:49:43

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:47:07
User closed query 'PV Query: Severity grade was reported as grade 2/moderate. The subject was hospitalized so please reassess the severity grade.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 13:46:59
Query 'PV Query: Severity grade was reported as grade 2/moderate. The subject was hospitalized so please reassess the severity grade.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	29 Apr 2021 20:35:36
DataPoint Un-verified.	(b) (4)	
	Jennifer Molstead (b) (4)	29 Apr 2021 20:35:16
Signature has been broken.	(b) (4)	
	Jennifer Molstead (b) (4)	29 Apr 2021 20:35:16
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Per Query Resolution	(b) (4)	
User opened query 'PV Query: Severity grade was reported as grade 2/moderate. The subject was hospitalized so please reassess the severity grade.' (Site from Safety).	Jennifer Molstead (b) (4)	29 Apr 2021 20:35:16
	(b) (4), (b) (6)	29 Apr 2021 19:07:23
User signature succeeded.		
	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'I'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered '02 Apr 2021'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered '11 Apr 2021'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'No (N)'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	21 Apr 2021 13:49:43

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

None

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered '0'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'I'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'I'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	21 Apr 2021 15:06:21
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	21 Apr 2021 13:49:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered empty; reason for change Per Query Resolution	Jennifer Molstead (b) (4)	21 Apr 2021 15:06:21
	(b) (4)	
User entered 'Subject was hospitalized for abdominal hernia repair. During surgery it was noted that part of the bowel was intertwined in the hernia and was nicked. Awaiting further medical records for medication'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'updated' (Site from Safety).	Frank Eder (b) (4)	03 May 2021 23:00:14
DataPoint Un-verified.	Frank Eder (b) (4)	03 May 2021 22:59:53
Signature has been broken.	Frank Eder (b) (4)	03 May 2021 22:59:53
User entered 'SUBJECT WAS HOSPITALIZED FOR ABDOMINAL HERNIA REPAIR. DURING SURGERY IT WAS NOTED THAT PART OF THE BOWEL WAS INTERTWINED IN THE HERNIA AND WAS NICKED.Covid testing was negative. AWAITING FURTHER MEDICAL RECORDS FOR MEDICATION AND PROCEDURES.' reason for change: Per Query Resolution	Frank Eder (b) (4)	03 May 2021 22:59:53
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:07:40
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:06:13
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 19:05:54
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:39
User entered 'SUBJECT WAS HOSPITALIZED FOR ABDOMINAL HERNIA REPAIR. DURING SURGERY IT WAS NOTED THAT PART OF THE BOWEL WAS INTERTWINED IN THE HERNIA AND WAS NICKED. AWAITING FURTHER MEDICAL RECORDS FOR MEDICATION AND PROCEDURES.' reason for change: Per Query Resolution		
	Jennifer Molstead (b) (4)	21 Apr 2021 15:06:21
	(b) (4)	
User entered 'and procedures.'	Jennifer Molstead (b) (4)	21 Apr 2021 13:49:43
	(b) (4)	

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 13:49:43

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 13:49:43

US3402288

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:32

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

Audit	User	Time (GMT)
User entered '0'	System	21 Apr 2021 13:49:43

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:26:32

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:04:45
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:20:07

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 16:21:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 16:21:31
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 16:21:12
User entered 'METFORMIN'	Tarin Gordon (b) (4)	09 Aug 2020 16:20:53
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:20:53
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:20:53

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '500'	Tarin Gordon (b) (4)	09 Aug 2020 16:20:53
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'mg (mg)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:20:53

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:20:53
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	09 Aug 2020 16:20:53
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:20:53
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 16:20:53
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:20:53
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 17:44:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Tarin Gordon (b) (4)	09 Aug 2020 16:34:18
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 16:20:53
User entered 'UN UNK 2018'	Tarin Gordon (b) (4)	09 Aug 2020 16:20:53
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:20:53
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 16:20:53
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:20:53

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:20:53
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:20:53

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:20:53

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 16:20:53

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE, PRODUCTSYNONYM: TOPAMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 06:54:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 06:54:36
Data point term sent to Coder Coding entries removed.	System Tammy Kohn (b) (4)	30 Sep 2020 19:13:15 30 Sep 2020 19:12:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE, PRODUCTSYNONYM: TOPAMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 21:07:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 21:07:17
Data point term sent to Coder User entered 'TOPAMAX'	System Tarin Gordon (b) (4)	09 Aug 2020 16:22:12 09 Aug 2020 16:21:29

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Per MM, Please review indication and confirm/update as necessary' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 13:31:30
Query 'Per MM, Please review indication and confirm/update as necessary' answered with 'DIZZINESS CAUSED FROM MIGRAINES ' (Site from DM).	Tammy Kohn (b) (4)	30 Sep 2020 19:12:34
	(b) (4)	
User entered 'DIZZINESS CAUSED FROM MIGRAINES' reason for change: Data Entry Error	Tammy Kohn (b) (4)	30 Sep 2020 19:12:29
	(b) (4)	
User opened query 'Per MM, Please review indication and confirm/update as necessary' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 12:34:36
User entered 'DIZZINESS'	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '50'	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'mg (mg)'	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'twice daily (BID)'	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 17:44:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Tarin Gordon (b) (4)	09 Aug 2020 16:34:10
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 16:21:29
User entered 'UN UNK 2018'	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:21:29

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:21:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Aug 2020 16:21:29

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:21:29

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 16:21:29

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 16:23:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 16:23:31
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 16:23:13
User entered 'VITAMIN D3'	Tarin Gordon (b) (4)	09 Aug 2020 16:22:34
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:22:34
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'VITAMIN D DEFICIENCY'	Tarin Gordon (b) (4)	09 Aug 2020 16:22:34
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	10 Nov 2020 15:44:36
	(b) (4), (b) (6)	
User closed query 'Per source dose 50,500 IU. Please verify and update the correct Vitamin D3 dose.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 15:44:31
Query 'Per source dose 50,500 IU. Please verify and update the correct Vitamin D3 dose.' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	08 Nov 2020 12:36:13
DataPoint Un-verified.	(b) (4)	
	Jennifer Molstead (b) (4)	08 Nov 2020 12:36:06
User entered '50,500' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	08 Nov 2020 12:36:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User opened query 'Per source dose 50,500 IU. Please verify and update the correct Vitamin D3 dose.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 20:08:32
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:02:10
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4)	20 Oct 2020 13:57:22
	(b) (4)	
User entered '5000' reason for change: Data Entry Error	Tammy Kohn (b) (4)	20 Oct 2020 13:57:14
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 06:09:59

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50500'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:22:34

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'IU (IU)'	Tarin Gordon (b) (4)	09 Aug 2020 16:22:34
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:22:34
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'other (OTHER)'	Tarin Gordon (b) (4)	09 Aug 2020 16:22:34
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'TWICE WEEKLY'	Tarin Gordon (b) (4)	09 Aug 2020 16:22:34
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 16:22:34
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:22:34
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 17:44:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	09 Aug 2020 16:34:05
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 16:22:34
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	09 Aug 2020 16:22:34
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:22:34
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:22:34

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:22:34

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:22:34
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:22:34

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:22:34

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:22:34

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 16:24:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 16:24:31
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 16:24:13
User entered 'OMEPRAZOLE'	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:23:13

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '40'	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'mg (mg)'	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 17:44:20
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Tarin Gordon (b) (4)	09 Aug 2020 16:33:59
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 16:23:13
User entered 'UN UNK 2019'	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:23:13

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:23:13
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:23:13

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:23:13

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 16:23:13

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
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)	09 Aug 2020 16:25:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 16:25:31
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 16:25:14
User entered 'ATORVASTATIN'	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'HYPERLIPIDEMIA'	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '40'	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'mg (mg)'	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 17:44:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Tarin Gordon (b) (4)	09 Aug 2020 16:33:54
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 16:24:55
User entered 'UN UNK 2017'	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:24:55
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:24:55

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:24:55

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 16:24:55

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 12:27:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 12:27:11
Data point term sent to Coder	System	09 Aug 2020 16:26:14
User entered 'HYDROCHLOROTHIAZIDE'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:25:51

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'HYPERENSION'	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '25'	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'mg (mg)'	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 17:44:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	09 Aug 2020 16:33:48
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 16:25:51
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:25:51

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:25:51
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:25:51

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:25:51

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 16:25:51

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:22:12
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:22:12
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 16:27:15
User entered 'ESTRADIOL'	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Per DM CLR: Please update the indication to reflect the location if Left, Right, or Bilateral and type if Benign or Malignant. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 17:40:47
Query 'Per DM CLR: Please update the indication to reflect the location if Left, Right, or Bilateral and type if Benign or Malignant. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'BILATERAL ' (Site from DM).	Tammy Kohn (b) (4)	25 Sep 2020 12:46:54
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location if Left, Right, or Bilateral and type if Benign or Malignant. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 02:17:21
User entered 'OVARIAN CYSTS'	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'I'	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'mg (mg)'	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 17:44:32
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Tarin Gordon (b) (4)	09 Aug 2020 16:33:40
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 16:26:46
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:46:21
DataPoint Un-verified.	Jennifer Molstead (b) (4)	08 Nov 2020 12:37:35
User entered 'Yes (Y)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	08 Nov 2020 12:37:35
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Per DM CLR: The corresponding Medical History has resolved, however the medication is still ongoing. Please verify and update stop dates for Medical History and/or medication as appropriate. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	21 Oct 2020 12:02:26
' (Site from DM).		
Query 'Per DM CLR: The corresponding Medical History has resolved, however the medication is still ongoing. Please verify and update stop dates for Medical History and/or medication as appropriate. Otherwise, provide clarification for continued use of medication.	Tammy Kohn (b) (4)	20 Oct 2020 13:58:23
' answered with 'DATA UPDATED' (Site from DM).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	20 Oct 2020 13:58:11
User opened query 'Per DM CLR: The corresponding Medical History has resolved, however the medication is still ongoing. Please verify and update stop dates for Medical History and/or medication as appropriate. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	20 Oct 2020 06:10:35
' (Site from DM).		
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:46:25
User closed query 'Per source this is marked as ongoing - Please verify and update accordingly.' (Site from CRA).		10 Nov 2020 15:46:18
Query 'Per source this is marked as ongoing - Please verify and update accordingly.' answered with 'UPdated' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:37:41
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:37:35
User entered empty; reason for change Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:37:35
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User opened query 'Per source this is marked as ongoing - Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 20:11:58
User entered 'UN UNK 2015' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Oct 2020 13:58:11
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:26:46

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:26:46
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:26:46

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:26:46

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 16:26:46

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: POLYETHYLENE GLYCOL 3350 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 06:52:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 06:52:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:46:40
User closed query 'Per source Polyethylene Glycol 3350. Please verify and update for consistency. ' (Site from CRA).		10 Nov 2020 15:46:35
Data point term sent to Coder	System	08 Nov 2020 12:39:38
Query 'Per source Polyethylene Glycol 3350. Please verify and update for consistency. ' answered with 'UPdated' (Site from CRA).	Jennifer Molstead (b) (4)	08 Nov 2020 12:38:54
DataPoint Un-verified.	Jennifer Molstead (b) (4)	08 Nov 2020 12:38:47
Coding entries removed.	Jennifer Molstead (b) (4)	08 Nov 2020 12:38:47
User entered 'POLYETHYLNE GLYCOL 3350' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	08 Nov 2020 12:38:47
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User opened query 'Per source Polyethylene Glycol 3350. Please verify and update for consistency. ' (Site from CRA).		07 Nov 2020 20:14:25

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 18:53:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 18:53:59
Data point term sent to Coder	System	09 Aug 2020 16:28:15
User entered 'POLYETHYLNE GLYCOL'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:28:08

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'CONSTIPATION'	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '17'	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'g (g)'	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'as needed (PRN)'	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 17:44:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Tarin Gordon (b) (4)	09 Aug 2020 16:33:34
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 16:28:08
User entered 'UN UNK 2017'	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:28:08
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:28:08

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:28:08

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:28:08

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 16:31:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 16:31:32
Data point term sent to Coder	System	09 Aug 2020 16:30:15
User entered 'CLONAZEPAM'	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'ANXIETY'	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0.5'	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'mg (mg)'	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'as needed (PRN)'	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:29:29

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 17:44:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Tarin Gordon (b) (4)	09 Aug 2020 16:33:28
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 16:29:29
User entered 'UN UNK 1986'	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:29:29

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:29:29
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:29:29

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:29:29

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:29:29

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: ANORO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 17:16:17
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 17:16:17
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 16:31:16
User entered 'ANORO (Umeclidinium-Vilanterol)'	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'ASTHMA'	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '62.5/25'	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'ug (ug)'	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 17:44:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	09 Aug 2020 16:33:22
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 16:30:49
User entered 'UN UNK 2019'	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:30:49
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:30:49

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 16:30:49

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 16:30:49

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:54:14
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:54:14
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 16:32:16
User entered 'ALBUTEROL SULFATE HFA'	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'ASTHMA'	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '90'	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'ug (ug)'	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'as needed (PRN)'	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 17:44:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Tarin Gordon (b) (4)	09 Aug 2020 16:33:17
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 16:31:42
User entered 'UN UNK 1998'	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:31:42
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:31:42

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:31:42

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:31:42

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:54:14
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 13:54:14
	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 16:33:18
User entered 'ALBUTEROL SOLUTION'	Tarin Gordon (b) (4)	09 Aug 2020 16:32:48
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:32:48
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'ASTHMA'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:32:48

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:16:22
User closed query 'Per source - 2.5mg/3ml. Please verify and update for consistency. ' (Site from CRA).		10 Nov 2020 18:16:20
Query 'Per source - 2.5mg/3ml. Please verify and update for consistency. ' answered with 'Updated' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:41:18
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:41:11
User entered '2.5/3' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	08 Nov 2020 12:41:11
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User opened query 'Per source - 2.5mg/3ml. Please verify and update for consistency. ' (Site from CRA).		07 Nov 2020 20:15:56
User entered '2.5'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:32:48

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:04:48
DataPoint Un-verified.	Jennifer Molstead (b) (4)	08 Nov 2020 12:41:11
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Jennifer Molstead (b) (4)	08 Nov 2020 12:41:11
Per Query Resolution	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'mg (mg)'	Tarin Gordon (b) (4)	09 Aug 2020 16:32:48
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:04:50
DataPoint Un-verified.	Jennifer Molstead (b) (4)	08 Nov 2020 12:41:11
	(b) (4)	
User entered 'mg/ml' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	08 Nov 2020 12:41:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:32:48
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'as needed (PRN)'	Tarin Gordon (b) (4)	09 Aug 2020 16:32:48
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:32:48
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Tarin Gordon (b) (4)	09 Aug 2020 16:32:48
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 16:32:48
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 17:44:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	09 Aug 2020 16:33:09
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 16:32:48
User entered 'UN UNK 1998'	Tarin Gordon (b) (4)	09 Aug 2020 16:32:48
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 16:32:48
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:32:48

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered empty.	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 16:32:48

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 20:16:11
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 16:32:48
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:32:48

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:32:48

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 16:32:48

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
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)	04 Feb 2021 12:50:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 12:50:48
Data point term sent to Coder	System	04 Feb 2021 12:50:37
Coding entries removed.	Tammy Kohn (b) (4)	04 Feb 2021 12:50:22
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)	30 Dec 2020 14:19:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Dec 2020 14:19:32
Data point term sent to Coder	System	30 Dec 2020 13:16:27
User entered 'amoxicillin'	Traci Hull (b) (4)	30 Dec 2020 13:16:10

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	30 Dec 2020 13:16:10
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
	(b) (4)	
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
User entered 'ABCESSED TOOTH' reason for change: Data Entry Error	Tammy Kohn (b) (4)	04 Feb 2021 12:50:22
	(b) (4)	
User entered 'toothaches'	Traci Hull (b) (4)	30 Dec 2020 13:16:10
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
User entered '500'	Traci Hull (b) (4)	30 Dec 2020 13:16:10
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
User entered 'mg (mg)'	Traci Hull (b) (4)	30 Dec 2020 13:16:10

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Dec 2020 13:16:10
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
User entered 'twice daily (BID)'	Traci Hull (b) (4)	30 Dec 2020 13:16:10
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
User entered empty.	Traci Hull (b) (4)	30 Dec 2020 13:16:10

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	30 Dec 2020 13:16:10
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
User entered empty.	Traci Hull (b) (4)	30 Dec 2020 13:16:10

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
User entered '21 Dec 2020'	Traci Hull (b) (4)	30 Dec 2020 13:16:10
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	30 Dec 2020 13:16:10
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	30 Dec 2020 13:16:10
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
User entered '29 Dec 2020'	Traci Hull (b) (4)	30 Dec 2020 13:16:10
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	30 Dec 2020 13:16:10
	(b) (4)	

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
User entered '2'	System	30 Dec 2020 13:16:10

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
User entered '1'	System	30 Dec 2020 13:16:10

US3402288

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:43:49
User entered '804 (804)'	System	30 Dec 2020 13:16:10

US3402288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:26:32

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:33:46
DataPoint Un-verified.	Jennifer Molstead (b) (4)	23 Apr 2021 13:15:11
Signature has been broken.	(b) (4) Jennifer Molstead (b) (4)	23 Apr 2021 13:15:11
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Jennifer Molstead (b) (4)	23 Apr 2021 13:15:11
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 20:16:40
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 15:18:32

US3402288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:26:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
User entered '02 Apr 2021'	Jennifer Molstead (b) (4)	23 Apr 2021 13:15:55
	(b) (4)	

US3402288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:26:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
User entered 'Abdominal Hernia Repair'	Jennifer Molstead (b) (4)	23 Apr 2021 13:15:55
	(b) (4)	

US3402288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:26:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	23 Apr 2021 13:15:55
	(b) (4)	

US3402288

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:26:32

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:24
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	23 Apr 2021 13:15:55
	(b) (4)	

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:14
User entered 'USA-US059-2021-MRNA-1273-P301000015'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Yes (Y)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Yes (Y)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Frank'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Eder'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered '1290 Upper Front Street'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Binghamton'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'NY'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered '13901'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:47:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
User entered 'US'	System	22 Apr 2021 13:12:23

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 13:47:36
User entered '1'	System	22 Apr 2021 13:12:23

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:14
User entered 'USA-US059-2021-MRNA-1273-P301000015'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Yes (Y)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Yes (Y)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Frank'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Eder'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered '1290 Upper Front Street'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Binghamton'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'NY'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered '13901'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:47:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
User entered 'US'	System	22 Apr 2021 13:12:23

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 13:47:36
User entered '1'	System	22 Apr 2021 13:12:23

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:26:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
User entered '22/Apr/2021 09:12'	System	22 Apr 2021 13:12:23

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:26:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:47:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 13:12:23

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:14
User entered 'USA-US059-2021-MRNA-1273-P301000015'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Yes (Y)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Yes (Y)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'No (N)'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Frank'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Eder'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered '1290 Upper Front Street'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'Binghamton'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered 'NY'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:12:17
User entered '13901'	System	21 Apr 2021 19:10:57

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:47:15
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:04:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:22:45
User entered 'US'	System	22 Apr 2021 13:12:23

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 13:47:36
User entered '1'	System	22 Apr 2021 13:12:23

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:26:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:28
User entered '30/Apr/2021 08:47'	(b) (4) System	30 Apr 2021 13:47:36

US3402288

Folder: SAE USA-US059-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:26:32

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)	03 May 2021 22:58:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:47:36