US3402420 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:22:36

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US3402420
Form: Participant Creation
Data signed: (b) (4) **26 Apr 2021 23:51:24**
Generated On: 09 Jun 2021 17:22:36

Participant ID   US3402420

mRNA-1273-P301 Completion Guidelines

US3402420

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **08 Mar 2021 22:45:18**

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	22 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 08 Mar 2021 22:45:15

Generated On: 09 Jun 2021 17:22:36

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female ◯
	Male ⬤
Ethnicity	Hispanic or Latino ◯
	Not Hispanic or Latino ⬤
	Not Reported ◯
	Unknown ◯

Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) **08 Mar 2021 22:45:15**

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Date of Informed Consent *(dd MMM yyyy)*	22 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020

Protocol Version
- Amendment 1 ○
- Amendment 2 ●
- Amendment 3 ○
- Amendment 4 ○
- Amendment 5 ○

Was participant enrolled in the study?
- Yes ●
- No ○

If No, indicate reason for screen fail
- Withdrew Consent ○
- Inclusion/Exclusion ○
- Cohort Full ○
- Other ○

If reason for screen fail is Other, specify _____

Was this participant screened previously?
- Yes ○
- No ●

If Yes, previous participant number _____

Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **08 Mar 2021 22:45:15**

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Did the participant meet all eligibility criteria?   Yes ●

                                                                     No ○

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) **08 Mar 2021 22:45:15**

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Were any significant conditions reported?   Yes ●

                                                                             No ◯

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **08 Mar 2021 22:45:15**

Generated On: 09 Jun 2021 17:22:36

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	29 DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	29 DEC 2019
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	DEC 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **08 Mar 2021 22:45:15**

Generated On: 09 Jun 2021 17:22:36

Condition	ANGIOPLASTY
Start date (dd MMM yyyy)	29 DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ⭕
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	29 DEC 2019
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	DEC 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **08 Mar 2021 22:45:15**

Generated On: 09 Jun 2021 17:22:36

Condition	STENT PLACEMENT
Start date (dd MMM yyyy)	29 DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	29 DEC 2019
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	DEC 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **08 Mar 2021 22:45:15**

Generated On: 09 Jun 2021 17:22:36

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	29 DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Mar 2021 22:45:15

Generated On: 09 Jun 2021 17:22:36

Condition	ANXIETY
Start date (dd MMM yyyy)	01 JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **08 Mar 2021 22:45:15**

Generated On: 09 Jun 2021 17:22:36

Condition	INSOMNIA
Start date (dd MMM yyyy)	01 JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **08 Mar 2021 22:45:15**

Generated On: 09 Jun 2021 17:22:36

Condition	CODEINE ALLERGY
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) **08 Mar 2021 22:45:15**

Generated On: 09 Jun 2021 17:22:36

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) **08 Mar 2021 22:45:15**

Generated On: 09 Jun 2021 17:22:36

Condition	CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	29 DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Mar 2021 22:45:15

Generated On: 09 Jun 2021 17:22:36

Condition	CARDIAC DISRHYTHMIA
Start date (dd MMM yyyy)	29 DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) **08 Mar 2021 22:45:15**

Generated On: 09 Jun 2021 17:22:36

Condition	GASTROESAPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) **08 Mar 2021 22:45:15**

Generated On: 09 Jun 2021 17:22:36

Condition	ANGIOPLASTY
Start date (dd MMM yyyy)	28 JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ○
	No ●
If No, please specify the stop date (dd MMM yyyy)	28 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) **08 Mar 2021 22:45:15**

Generated On: 09 Jun 2021 17:22:36

Condition	STENT PLACEMENT
Start date (dd MMM yyyy)	28 JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ⚪
	No ⚫
If No, please specify the stop date (dd MMM yyyy)	28 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **08 Mar 2021 22:45:18**

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?	Yes ●
	No ◯
Date of assessment *(dd MMM yyyy)*	22 AUG 2020
Time of assessment *(00:00-23:59)*	08:30 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 08:30
Height *(xxx.x)*	176 cm
Weight *(xxx.x)*	95.2 kg
BMI *(xxx.x)*	30.73347 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ◯
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **08 Mar 2021 22:45:15**

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Was the physical examination performed? Yes ●

No ○

Date of examination *(dd MMM yyyy)* 22 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 08 Mar 2021 22:45:15

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ◯ No ⬤	
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ◯ No ⬤	
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ◯ No ⬤	
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ◯ No ⬤	
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ◯ No ⬤	
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ◯ No ⬤	
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ◯ No ⬤	
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ◯ No ⬤	
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ◯ No ⬤	
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ◯ No ⬤	
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ◯ No ⬤	
Other	Yes ⬤ No ◯	
Specify	IN PUBLIC OVER THREE TIMES PER WEEK	

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **08 Mar 2021 22:45:15**

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	22 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **15 Feb 2021 18:27:50**

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What was the date of randomization? *(dd MMM yyyy)*	22 AUG 2020
What was the participant's randomization number?	144744

In what Cohort was the participant enrolled?

- >=18 and <65 years and not at risk ⚪
- >=18 and <65 years and at risk ⚫
- >=65 years ⚪

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

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

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Yes ⚫
- No ⚪

Severe obesity (body mass index > or = 40kg/m2)
- Yes ⚪
- No ⚫

Diabetes (Type I, Type 2, or gestational)
- Yes ⚪
- No ⚫

Liver Disease
- Yes ⚪
- No ⚫

Human Immunodeficiency Virus (HIV) infection
- Yes ⚪
- No ⚫

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **15 Feb 2021 18:27:50**

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ●
	Post-Dose ◯
Were vital signs assessed?	Yes ●
	No ◯
Date of assessment *(dd MMM yyyy)*	22 AUG 2020
Time of assessment *(00:00-23:59)*	08:30 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 08:30
Temperature *(xxx.x)*	36.3 C
Route of measurement	Oral ●
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	58 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	60 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	22 AUG 2020
Time of assessment *(00:00-23:59)*	09:54 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 09:54
Temperature *(xxx.x)*	36.0 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	54 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	64 mmHg
Diastolic Blood Pressure units	MMHG

Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 18:27:50**
Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   22 AUG 2020

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

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)*	22 AUG 2020
What was the treatment time? *(00:00-23:59)*	09:23 (24 HR)
Treatment Date and Time (derived)	22 AUG 2020 09:23
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

Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 18:27:50**
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Was the sample collected?   Yes ●

               No ○

Collection date *(dd MMM yyyy)*	22 AUG 2020
Collection time *(00:00-23:59)*	09:09 (24 HR)
Collection date and time (derived)	22 AUG 2020 09:09

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **15 Feb 2021 18:27:50**

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Collection date *(dd MMM yyyy)*			22 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:45	22 AUG 2020 08:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 18:27:50**

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Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

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**	96.8 °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	22 AUG 2020 09:55
PC Open Date & Time	22 AUG 2020 09:43
PC Close Date & Time	22 AUG 2020 12:13

TIMEPOINT	DAY 1, AFTER VACCINATION
	(AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	22 AUG 2020 18:59
PC Open Date & Time	22 AUG 2020 13:08
PC Close Date & Time	23 AUG 2020 11:59

TIMEPOINT	DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.8 °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	23 AUG 2020 13:25
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

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	24 AUG 2020 16:04
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ⬤
	No ◯

Please record your **TEMPERATURE in °F**	97.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ⬤

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

PC Time Stamp	25 AUG 2020 17:16
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:22:36

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**	96.4 °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	26 AUG 2020 16:34
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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**	97.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	27 AUG 2020 22:08
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

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**	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	28 AUG 2020 14:30
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

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US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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	22 AUG 2020 09:56
PC Open Date & Time	22 AUG 2020 09:43
PC Close Date & Time	22 AUG 2020 12:13

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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	22 AUG 2020 18:59
PC Open Date & Time	22 AUG 2020 13:08
PC Close Date & Time	23 AUG 2020 11:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 2
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	23 AUG 2020 13:25
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 3

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	24 AUG 2020 16:04
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 4
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	25 AUG 2020 17:17
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 5
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	26 AUG 2020 16:35
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 6

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	27 AUG 2020 22:08
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 7
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	28 AUG 2020 14:30
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 ○

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	22 AUG 2020 09:56
PC Open Date & Time	22 AUG 2020 09:43
PC Close Date & Time	22 AUG 2020 12:13

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 ◯

| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ⬤ |
| | Yes ◯ |

PC Time stamp	22 AUG 2020 19:00
PC Open Date & Time	22 AUG 2020 13:08
PC Close Date & Time	23 AUG 2020 11:59

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36

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 ●

Yes ◯

PC Time stamp	23 AUG 2020 13:26
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:22:36

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 ●

Yes ◯

PC Time stamp	24 AUG 2020 16:05
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 ⬤

	Yes ◯
PC Time stamp	25 AUG 2020 17:17
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36

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 ⬤

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

	Yes ◯
PC Time stamp	26 AUG 2020 16:35
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36

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 ●

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36

	Yes ◯
PC Time stamp	27 AUG 2020 22:08
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

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 ●

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:22:36

	Yes ◯
PC Time stamp	28 AUG 2020 14:31
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3402420

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

| 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

US3402420

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ⬤

                                                          No ◯

Continuing Flag   1

US3402420

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 8 SEP 2020 |

| Please select one status for the follow-up contact | Contact Made ⬤ |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments

US3402420

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ●

                                                                                            No ○

Continuing Flag   1

US3402420

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 12 SEP 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments _____

US3402420

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3402420
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 18:27:51**
Generated On: 09 Jun 2021 17:22:36

| Was this visit performed? | Yes ● |
| | No ○ |

| Visit date (dd MMM yyyy) | 23 SEP 2020 |

| Was visit performed at the participant's home or at the clinic? | Home ○ |
| | Clinic ● |

| Folder OID | VISIT2 |

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **15 Feb 2021 18:27:51**

Generated On: 09 Jun 2021 17:22:36

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	23 SEP 2020
Time of assessment *(00:00-23:59)*	07:36 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 07:36
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	62 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **15 Feb 2021 18:27:51**

Generated On: 09 Jun 2021 17:22:36

Timepoint	Pre-Dose ○
	Post-Dose ●
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	23 SEP 2020
Time of assessment *(00:00-23:59)*	08:41 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 08:41
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	57 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

US3402420

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?   Yes ●

                                                                            No ○

Date of examination *(dd MMM yyyy)*   23 SEP 2020

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

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)*	23 SEP 2020
What was the treatment time? *(00:00-23:59)*	08:10 (24 HR)
Treatment Date and Time (derived)	23 SEP 2020 08:10
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3402420

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	23 SEP 2020
Collection time *(00:00-23:59)*	07:48 (24 HR)
Collection date and time (derived)	23 SEP 2020 07:48

US3402420

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Collection date *(dd MMM yyyy)*			23 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:51	23 SEP 2020 07:51
Nasopharyngeal Swab 2	No		

US3402420

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　1

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**	97.9 °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	23 SEP 2020 08:41
PC Open Date & Time	23 SEP 2020 08:30
PC Close Date & Time	23 SEP 2020 11:00

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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	23 SEP 2020 21:55
PC Open Date & Time	23 SEP 2020 11:55
PC Close Date & Time	24 SEP 2020 11:59

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	24 SEP 2020 20:02
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

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**	97.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	25 SEP 2020 13:19
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

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**	96.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	26 SEP 2020 12:15
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ⬤
	No ◯
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ⬤

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

PC Time Stamp	27 SEP 2020 12:34
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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**	95.9 °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	28 SEP 2020 16:59
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

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**	96.8 °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	29 SEP 2020 20:55
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-1770993

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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	23 SEP 2020 08:43
PC Open Date & Time	23 SEP 2020 08:30
PC Close Date & Time	23 SEP 2020 11:00

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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	23 SEP 2020 21:56
PC Open Date & Time	23 SEP 2020 11:55
PC Close Date & Time	24 SEP 2020 11:59

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 2
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	24 SEP 2020 20:02
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

TIMEPOINT	DAY 3

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	25 SEP 2020 13:20
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 4
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	26 SEP 2020 12:15
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 5
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	27 SEP 2020 12:34
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

TIMEPOINT	DAY 6
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	28 SEP 2020 17:00
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 7

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	29 SEP 2020 20:55
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 ◯

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○

PC Time stamp	23 SEP 2020 08:43
PC Open Date & Time	23 SEP 2020 08:30
PC Close Date & Time	23 SEP 2020 11:00

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:22:36

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 ◯

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	23 SEP 2020 21:57
PC Open Date & Time	23 SEP 2020 11:55
PC Close Date & Time	24 SEP 2020 11:59

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36

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 ●

	Yes ◯
PC Time stamp	24 SEP 2020 20:03
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:22:36

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 ●

	Yes ◯
PC Time stamp	25 SEP 2020 13:21
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:22:36

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 ●

	Yes ◯
PC Time stamp	26 SEP 2020 12:16
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

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 ⬤

FDA-CBER-2022-1614-1771012

	Yes ◯
PC Time stamp	27 SEP 2020 12:35
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36

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 ⬤

FDA-CBER-2022-1614-1771014

	Yes ◯
PC Time stamp	28 SEP 2020 17:00
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:22:36

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 ●

	Yes ⭕
PC Time stamp	29 SEP 2020 20:55
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-1771017

US3402420
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 18:27:50**
Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?   Yes ⬤

                                                                             No ◯

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

Please select one status for the follow-up contact   Contact Made ⬤

                                                        Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3402420

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ⬤

                                                                No ◯

Continuing Flag   1

US3402420

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	7 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3402420

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ⬤

                                                                     No ◯

Continuing Flag   1

US3402420

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 OCT 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments _____

US3402420

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 18:27:50**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ●

                                                                                     No ○

Continuing Flag   1

US3402420
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 18:27:51**
Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT3

US3402420

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **15 Feb 2021 18:27:51**

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	27 OCT 2020
Time of assessment *(00:00-23:59)*	08:11 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 08:11
Temperature *(xxx.x)*	36.2 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	62 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402420

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4)   **15 Feb 2021 18:27:51**

Generated On: 09 Jun 2021 17:22:36

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.

US3402420

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **15 Feb 2021 18:27:51**

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	27 OCT 2020
Collection time *(00:00-23:59)*	08:15 (24 HR)
Collection date and time (derived)	27 OCT 2020 08:15

US3402420

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 18:27:51**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-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	25 OCT 2020 09:33:32
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	31 OCT 2020 13:50:34
Patient Cloud Open Date & Time	29 OCT 2020 00:01
Patient Cloud Close Date & Time	02 NOV 2020 23:59

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 ⚪
Have 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):	
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 ⚪
Date and time of submission	08 NOV 2020 10:53:48
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ≥ 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 ○

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-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	25 NOV 2020 08:39:43
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 17:59:33
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

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	07 DEC 2020 08:54:23
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 06:14:56
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 16:58:05
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 19:33:03
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	04 JAN 2021 10:39:01
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	11 JAN 2021 09:03:42
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	18 JAN 2021 08:16:45
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	25 JAN 2021 08:37:15
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 09:47:10
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	08 FEB 2021 20:43:06
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	18 FEB 2021 12:24:09
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 09:26:12
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 08:05:07
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	10 MAR 2021 12:01:20
Patient Cloud Open Date & Time	08 MAR 2021 00:01
Patient Cloud Close Date & Time	12 MAR 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	17 MAR 2021 20:55:43
Patient Cloud Open Date & Time	15 MAR 2021 00:01
Patient Cloud Close Date & Time	19 MAR 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	23 MAR 2021 11:56:27
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	31 MAR 2021 18:25:00
Patient Cloud Open Date & Time	29 MAR 2021 00:01
Patient Cloud Close Date & Time	02 APR 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	05 APR 2021 13:15:17
Patient Cloud Open Date & Time	05 APR 2021 00:01
Patient Cloud Close Date & Time	09 APR 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	12 APR 2021 08:26:32
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 APR 2021 13:20:05
Patient Cloud Open Date & Time	19 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	26 APR 2021 08:07:25
Patient Cloud Open Date & Time	26 APR 2021 00:01
Patient Cloud Close Date & Time	30 APR 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	03 MAY 2021 10:52:15
Patient Cloud Open Date & Time	03 MAY 2021 00:01
Patient Cloud Close Date & Time	07 MAY 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 264

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature ≥ 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 ⃝

FDA-CBER-2022-1614-1771058

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	17 MAY 2021 00:01
Patient Cloud Close Date & Time	21 MAY 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT　　　　　　　　　　　　　　　　　　　**DAY 278**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-1771062

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   **DAY 285**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
Fever (Temperature ≥ 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 ⃝

FDA-CBER-2022-1614-1771064

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	31 MAY 2021 00:01
Patient Cloud Close Date & Time	04 JUN 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 292

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-1771066

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	07 JUN 2021 00:01
Patient Cloud Close Date & Time	11 JUN 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

Symptom	
Fever (Temperature ≥ 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 ⬭

FDA-CBER-2022-1614-1771068

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	14 JUN 2021 00:01
Patient Cloud Close Date & Time	18 JUN 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	**DAY 306**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	21 JUN 2021 00:01
Patient Cloud Close Date & Time	25 JUN 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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):

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-1771072

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 JUN 2021 00:01
Patient Cloud Close Date & Time	02 JUL 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	12 JUL 2021 00:01
Patient Cloud Close Date & Time	16 JUL 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

FDA-CBER-2022-1614-1771080

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	26 JUL 2021 00:01
Patient Cloud Close Date & Time	30 JUL 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-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 ⭕

FDA-CBER-2022-1614-1771082

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	02 AUG 2021 00:01
Patient Cloud Close Date & Time	06 AUG 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 AUG 2021 00:01
Patient Cloud Close Date & Time	13 AUG 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	**DAY 362**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature $\geq$ 100.4°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 ⃝

FDA-CBER-2022-1614-1771086

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	**DAY 369**

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

No ◯
Yes ◯

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

No ◯
Yes ◯

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

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

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

No ◯
Yes ◯

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

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

No ◯
Yes ◯

FDA-CBER-2022-1614-1771088

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
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 ⬭

FDA-CBER-2022-1614-1771090

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	03 SEP 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	**DAY 383**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-1771092

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	06 SEP 2021 00:01
Patient Cloud Close Date & Time	10 SEP 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT DAY 390

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 SEP 2021 00:01
Patient Cloud Close Date & Time	17 SEP 2021 23:59

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36

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°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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	20 SEP 2021 00:01
Patient Cloud Close Date & Time	24 SEP 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	04 OCT 2021 00:01
Patient Cloud Close Date & Time	08 OCT 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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 ⃝

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	11 OCT 2021 00:01
Patient Cloud Close Date & Time	15 OCT 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

FDA-CBER-2022-1614-1771104

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 OCT 2021 00:01
Patient Cloud Close Date & Time	22 OCT 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Symptom	
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 ⃝

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 439

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

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

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

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

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-1771108

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ⃝

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	08 NOV 2021 00:01
Patient Cloud Close Date & Time	12 NOV 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ≥ 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 ◯

FDA-CBER-2022-1614-1771112

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	15 NOV 2021 00:01
Patient Cloud Close Date & Time	19 NOV 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

FDA-CBER-2022-1614-1771114

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 NOV 2021 00:01
Patient Cloud Close Date & Time	26 NOV 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	03 DEC 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	06 DEC 2021 00:01
Patient Cloud Close Date & Time	10 DEC 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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 ◯

FDA-CBER-2022-1614-1771120

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	**DAY 488**

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

FDA-CBER-2022-1614-1771122

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	20 DEC 2021 00:01
Patient Cloud Close Date & Time	24 DEC 2021 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	**DAY 502**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 JAN 2022 00:01
Patient Cloud Close Date & Time	07 JAN 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
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 ⬭

FDA-CBER-2022-1614-1771130

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	17 JAN 2022 00:01
Patient Cloud Close Date & Time	21 JAN 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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):

Symptom	
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 ⚪

FDA-CBER-2022-1614-1771134

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	31 JAN 2022 00:01
Patient Cloud Close Date & Time	04 FEB 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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):

Symptom	
Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-1771136

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	07 FEB 2022 00:01
Patient Cloud Close Date & Time	11 FEB 2022 23:59

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 ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

FDA-CBER-2022-1614-1771140

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	21 FEB 2022 00:01
Patient Cloud Close Date & Time	25 FEB 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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 ◯

FDA-CBER-2022-1614-1771142

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Date and time of submission	
Patient Cloud Open Date & Time	28 FEB 2022 00:01
Patient Cloud Close Date & Time	04 MAR 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	07 MAR 2022 00:01
Patient Cloud Close Date & Time	11 MAR 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	**DAY 572**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭
	Yes ⬭

FDA-CBER-2022-1614-1771146

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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 ◯

FDA-CBER-2022-1614-1771148

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	21 MAR 2022 00:01
Patient Cloud Close Date & Time	25 MAR 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT DAY 586

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

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

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

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

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

Fever (Temperature ≥ 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 ⦿

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 MAR 2022 00:01
Patient Cloud Close Date & Time	01 APR 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	04 APR 2022 00:01
Patient Cloud Close Date & Time	08 APR 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

FDA-CBER-2022-1614-1771154

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	11 APR 2022 00:01
Patient Cloud Close Date & Time	15 APR 2022 23:59

TIMEPOINT   DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-1771156

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 APR 2022 00:01
Patient Cloud Close Date & Time	22 APR 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ⬭

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	02 MAY 2022 00:01
Patient Cloud Close Date & Time	06 MAY 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ◯

FDA-CBER-2022-1614-1771162

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 MAY 2022 00:01
Patient Cloud Close Date & Time	13 MAY 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	16 MAY 2022 00:01
Patient Cloud Close Date & Time	20 MAY 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

FDA-CBER-2022-1614-1771168

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Fever (Temperature ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	06 JUN 2022 00:01
Patient Cloud Close Date & Time	10 JUN 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-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 ≥ 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 ⃝

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2022 00:01
Patient Cloud Close Date & Time	17 JUN 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

FDA-CBER-2022-1614-1771174

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	20 JUN 2022 00:01
Patient Cloud Close Date & Time	24 JUN 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ≥ 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 ◯

FDA-CBER-2022-1614-1771176

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT DAY 684

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

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

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

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

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	04 JUL 2022 00:01
Patient Cloud Close Date & Time	08 JUL 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	11 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-1771184

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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):

Symptom	
Fever (Temperature ≥ 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 ⬭

FDA-CBER-2022-1614-1771186

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT   DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⊝ Yes ⊝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⊝ Yes ⊝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⊝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⊝ Yes ⊝

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

Fever (Temperature ≥ 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 ⊝

FDA-CBER-2022-1614-1771188

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	08 AUG 2022 00:01
Patient Cloud Close Date & Time	12 AUG 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
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 ⬭

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	15 AUG 2022 00:01
Patient Cloud Close Date & Time	19 AUG 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT　　　　　　　　　　　　　　　　　　　　　　　**DAY 733**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

Fever (Temperature $\geq$ 100.4°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 ⃝

FDA-CBER-2022-1614-1771192

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2022 00:01
Patient Cloud Close Date & Time	26 AUG 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
Fever (Temperature ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	**DAY 747**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	05 SEP 2022 00:01
Patient Cloud Close Date & Time	09 SEP 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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 ◯

FDA-CBER-2022-1614-1771198

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	12 SEP 2022 00:01
Patient Cloud Close Date & Time	16 SEP 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature ≥ 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 ◯

FDA-CBER-2022-1614-1771202

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	26 SEP 2022 00:01
Patient Cloud Close Date & Time	30 SEP 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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 ○

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 OCT 2022 00:01
Patient Cloud Close Date & Time	07 OCT 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-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):

Symptom	
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 ⬭

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

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

Symptom	
Fever (Temperature ≥ 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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	17 OCT 2022 00:01
Patient Cloud Close Date & Time	21 OCT 2022 23:59

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 ◯

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2022 00:01
Patient Cloud Close Date & Time	28 OCT 2022 23:59

US3402420

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:22:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 18:33:11

US3402420
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **08 Mar 2021 22:32:20**
Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?   Yes ●

                                                                               No ○

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

Please select one status for the follow-up contact   Contact Made ●

                                                              Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3402420

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **08 Mar 2021 22:32:20**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ●

                                                                            No ○

Continuing Flag   1

US3402420

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 DEC 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3402420

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ●

                                                               No ○

Continuing Flag   1

US3402420
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 23:51:24**
Generated On: 09 Jun 2021 17:22:36

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3402420

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　1

US3402420

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **26 Apr 2021 23:51:25**

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 FEB 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3402420

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3402420

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) **26 Apr 2021 23:51:25**

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT4

US3402420

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) **26 Apr 2021 23:51:25**

Generated On: 09 Jun 2021 17:22:36

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) _____

FDA-CBER-2022-1614-1771222

Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Apr 2021 23:51:25**
Generated On: 09 Jun 2021 17:22:36

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.

US3402420

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4)   **26 Apr 2021 23:51:25**

Generated On: 09 Jun 2021 17:22:36

| Was the sample collected? | Yes ● |
| | No ◯ |

Collection date *(dd MMM yyyy)*	17 MAR 2021
Collection time *(00:00-23:59)*	10:07 (24 HR)
Collection date and time (derived)	17 MAR 2021 10:07

US3402420

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 23:51:25**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ●

                                                           No ◯

Continuing Flag   1

US3402420

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4)   **26 Apr 2021 23:51:25**

Generated On: 09 Jun 2021 17:22:36

| Was Contact Attempted? | Yes ● |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 19 APR 2021 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments

US3402420

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 23:51:25**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3402420
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:22:36

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 _____

Is the participant continuing to the next visit?   Yes ◯
                                                      No ◯

Continuing Flag

US3402420
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:22:36

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	

Type of Contact

Clinic Visit - Scheduled ◯
Clinical Visit - Unscheduled ◯
Safety Call ◯
Convalescent Tele-visit ◯

Has the subject reported symptoms of SARS-COV-2?

Yes ◯
No ◯

US3402420

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:22:36

| Generate Next COVID-19 Assessment | Yes | ⬭ |
| | No | ⬭ |

US3402420

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

Form: Visit Date

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	19 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

US3402420

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 23:51:24

Generated On: 09 Jun 2021 17:22:36

Date of updated informed consent *(dd MMM yyyy)*	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ●
	No ○
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ○
	Amendment 6 or later ●
Date of unblinding *(dd MMM yyyy)*	19 JAN 2021
Participant randomization assignment	mRNA-1273 ○
	Placebo ●
Actual Dose 1	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Actual Dose 2	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Will participant receive mRNA-1273?	Yes ●
	No ○
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3402420

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

Form: Vital Signs - Dosing

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

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

US3402420

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 23:51:24

Generated On: 09 Jun 2021 17:22:36

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	19 JAN 2021
Time of assessment *(00:00-23:59)*	08:42 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 08:42
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	58 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	77 mmHg
Diastolic Blood Pressure units	MMHG

US3402420

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	19 JAN 2021
Time of assessment *(00:00-23:59)*	09:28 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 09:28
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

US3402420

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

Form: Physical Examination

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?   Yes ●

                                                                        No ○

Date of examination *(dd MMM yyyy)*   19 JAN 2021

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

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

Form: Exposure

Data signed: ▨ (b) (4) ▨ **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Was study treatment given?	Yes ⬤
	No ◯

If No, reason not given	Participant declined due to Adverse Event ◯
	Physician withheld dose due to Adverse Event ◯
	Death ◯
	Lost To Follow-Up ◯
	Physician Decision ◯
	Pregnancy ◯
	Protocol Deviation ◯
	Study Terminated by Sponsor ◯
	Withdrawal of Consent by Participant ◯
	Confirmed COVID-19 ◯
	Other ◯

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	19 JAN 2021
What was the treatment time? *(00:00-23:59)*	08:55 (24 HR)
Treatment Date and Time (derived)	19 JAN 2021 08:55
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

US3402420

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	19 JAN 2021
Collection time *(00:00-23:59)*	08:28 (24 HR)
Collection date and time (derived)	19 JAN 2021 08:28

US3402420

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	19 JAN 2021
Collection time *(00:00 - 23:59)*	08:23
Collection Date and Time (derived)	19 JAN 2021 08:23

US3402420

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

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?　　　　　　Yes ●

No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　1

US3402420

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) **26 Apr 2021 23:51:25**

Generated On: 09 Jun 2021 17:22:36

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3402420

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 23:51:25**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Continuing Flag	1
OLD29 Placebo Flag	1

US3402420

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	16 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	OLD29

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	16 FEB 2021
Time of assessment *(00:00-23:59)*	08:15 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 08:15
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	65 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1771245

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	16 FEB 2021
Time of assessment *(00:00-23:59)*	09:33 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 09:33
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	51 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	68 mmHg
Diastolic Blood Pressure units	MMHG

US3402420

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?   Yes ●

                                                  No ○

Date of examination *(dd MMM yyyy)*   16 FEB 2021

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

US3402420

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4)   26 Apr 2021 23:51:24

Generated On: 09 Jun 2021 17:22:36

Was study treatment given?	Yes ●
	No ○
If No, reason not given	Participant declined due to Adverse Event ○
	Physician withheld dose due to Adverse Event ○
	Death ○
	Lost To Follow-Up ○
	Physician Decision ○
	Pregnancy ○
	Protocol Deviation ○
	Study Terminated by Sponsor ○
	Withdrawal of Consent by Participant ○
	Confirmed COVID-19 ○
	Other ○
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	16 FEB 2021
What was the treatment time? *(00:00-23:59)*	08:56 (24 HR)
Treatment Date and Time (derived)	16 FEB 2021 08:56
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

US3402420

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3402420

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) **26 Apr 2021 23:51:25**

Generated On: 09 Jun 2021 17:22:36

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 FEB 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3402420

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 23:51:25**

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?   Yes ⬤

                                                                                    No ◯

Continuing Flag   1

US3402420

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

| Was this visit performed? | Yes ● |
| | No ○ |

| Visit date (dd MMM yyyy) | 17 MAR 2021 |

| Was visit performed at the participant's home or at the clinic? | Home ○ |
| | Clinic ● |

| Folder OID | OLD57 |

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)

US3402420

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

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.

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	17 MAR 2021
Collection time *(00:00-23:59)*	10:07 (24 HR)
Collection date and time (derived)	17 MAR 2021 10:07

US3402420

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **26 Apr 2021 23:51:24**

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Did the participant experience any adverse events?   Yes ●

                                                                          No ◯

If Yes, enter details on the Adverse Events form.

US3402420

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **26 Apr 2021 23:51:24**

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AEID	USA-US059-2021-MRNA-1273-P30 1000014
Adverse event	UNSTABLE ANGINA

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)*	19 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ○ / No ●

If not Ongoing, end date *(dd MMM yyyy)*	24 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity Grade 1/Mild ○ / Grade 2/Moderate ● / Grade 3/Severe ○ / Grade 4 ○

Is the adverse event serious? Yes ● / No ○

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	23 MAR 2021
Hospital Discharge Date *(dd MMM yyyy)*	24 MAR 2021

Admitted to ICU? Yes ○ / No ● / Unknown ○

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US3402420

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 23:51:24

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

- None ◯
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ◯
- Not Recovered/Not Resolved ◯
- Recovered/Resolved ⬤
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ◯
- Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

PATIENT PRESENTED TO EMERGENCY ROOM WITH LEFT SIDED CHEST PAIN THAT HE HAD BEEN HAVING FOR 3-4 DAYS. PATIENT DENIED ANY CHANGES IN ACTIVITY. PATIENT DOES HAVE A HISTORY OF DEFIBRILLATOR AND MYOCARDIAL INFARCTION WITH 4 STENTS PLACED IN DECEMBER OF 2019. SUBJECT DID HAVE A CMP, PROTIME, APTT, AND TROPONIN ALL OF WHICH RETURNED NORMAL RESULTS.SUBJECTS LOOD PRESSURE RANGED FROM 112/82-120/84SUBJECT DID HAVE COVID TEST THAT WAS NEGATIVE. CHEST XRAY THAT WAS NEGATIVE, HE ALSO HAD A ECG THAT SHOWED BRADICARDIA HEART REATE OF 54, A PREVIOUS INFARCT IN THE ANTEROLATERAL/INFERIOR LEADS, BUTNO ACUTE ST WAVE CHANGES.SUBJECT ALSO HAD ECHO CARDIAGRAM WHCH SHOWED A DECREASE INEF OF 19% FROM PREVIOUS ECHO, AND A STRESS TEST WHICH SHOWED NO CHANGES. SUBJECT WILL CONTINUE ASPIRIN 81 MG, COREG 6.25 MG TWICE DAILY, BRILLINTA 90MG TWICE DAILY, AND ATORVASTATIN 40MG DAILY.

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

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **08 Apr 2021 23:44:07**

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

                                                                                        No ◯

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

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **08 Apr 2021 23:44:05**

Generated On: 09 Jun 2021 17:22:36

Name of Medication	AMIODARONE
Prophylaxis	Yes ⭕
	No ⚫
Indication	CARDIAC DYSRHYTHMIA
Dose per administration	200
Dose unit	mg ⚫
	ug ⭕
	mL ⭕
	g ⭕
	IU ⭕
	tablet ⭕
	capsule ⭕
	puff ⭕
	Other ⭕
If dose unit is Other, specify	
Frequency	once daily ⚫
	twice daily ⭕
	three times daily ⭕
	four times daily ⭕
	every other day ⭕
	every week ⭕
	every month ⭕
	as needed ⭕
	once ⭕
	unknown ⭕
	other ⭕
If frequency is Other, specify	
Route of administration	Oral ⚫
	Topical ⭕
	Subcutaneous ⭕
	Transdermal ⭕
	Intraocular ⭕

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **08 Apr 2021 23:44:05**
Generated On: 09 Jun 2021 17:22:36

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	03 JAN 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **08 Apr 2021 23:44:05**

Generated On: 09 Jun 2021 17:22:36

Name of Medication	ASPIRIN

Prophylaxis

Yes ⚪
No ⚫

Indication	CARDIAC DYSRHYTHMIA
Dose per administration	81

Dose unit

mg ⚫
ug ⚪
mL ⚪
g ⚪
IU ⚪
tablet ⚪
capsule ⚪
puff ⚪
Other ⚪

If dose unit is Other, specify _____

Frequency

once daily ⚫
twice daily ⚪
three times daily ⚪
four times daily ⚪
every other day ⚪
every week ⚪
every month ⚪
as needed ⚪
once ⚪
unknown ⚪
other ⚪

If frequency is Other, specify _____

Route of administration

Oral ⚫
Topical ⚪
Subcutaneous ⚪
Transdermal ⚪
Intraocular ⚪

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	03 JAN 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **08 Apr 2021 23:44:05**

Generated On: 09 Jun 2021 17:22:36

Name of Medication	ATORVASTATIN

Prophylaxis	Yes ○
	No ●

Indication	CORONARY ARTERY 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 ○
	Intraocular ○

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	03 JAN 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **08 Apr 2021 23:44:05**

Generated On: 09 Jun 2021 17:22:36

Name of Medication	CARVEDILOL

Prophylaxis	Yes ○
	No ⬤

Indication	CORONARY ARTERY DISEASE

Dose per administration	6.25

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 ○

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EAB) (1725)

	Intramuscular ⬭
	Respiratory (Inhalation) ⬭
	Intralesional ⬭
	Intraperiteoneal ⬭
	Nasal ⬭
	Vaginal ⬭
	Rectal ⬭
	Intravenous ⬭
	Intravenous Bolus ⬭
	Intravenous Drip ⬭
	Other ⬭

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	03 JAN 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ⬭
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ⬭
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ⬭
	803 ⬭
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **08 Apr 2021 23:44:05**

Generated On: 09 Jun 2021 17:22:36

Name of Medication	PANTOPRAZOLE

Prophylaxis

Yes ◯

No ⬤

Indication	GASTROESAPHAGEAL 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 ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯

If not Ongoing, End date *(dd MMM yyyy)*

Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **08 Apr 2021 23:44:05**

Generated On: 09 Jun 2021 17:22:36

Name of Medication	ENTRESTO (SACUBITRIL/VALSARTAN)

Prophylaxis	Yes	◯
	No	⬤

Indication	CONGESTIVE HEART FAILURE
Dose per administration	97/103

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	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperitoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	10 MAR 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **08 Apr 2021 23:44:05**

Generated On: 09 Jun 2021 17:22:36

Name of Medication	TICAGRELOR

Prophylaxis

Yes ◯
No ⬤

Indication	CARDIAC DYSRHYTHMIA
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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) **08 Apr 2021 23:44:05**

Generated On: 09 Jun 2021 17:22:36

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	03 JAN 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **08 Apr 2021 23:44:05**

Generated On: 09 Jun 2021 17:22:36

Name of Medication	ALPRAZOLAM

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 ○

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 MAR 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) **08 Apr 2021 23:44:05**

Generated On: 09 Jun 2021 17:22:36

Name of Medication	TRAZODONE

Prophylaxis

Yes ◯

No ●

Indication	INSOMNIA
Dose per administration	50

Dose unit

mg ●

ug ◯

mL ◯

g ◯

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ◯

If dose unit is Other, specify _____

Frequency

once daily ◯

twice daily ◯

three times daily ◯

four times daily ◯

every other day ◯

every week ◯

every month ◯

as needed ●

once ◯

unknown ◯

other ◯

If frequency is Other, specify _____

Route of administration

Oral ●

Topical ◯

Subcutaneous ◯

Transdermal ◯

Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 MAR 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Were any concomitant procedures performed?   Yes ●

No ◯

If yes, please complete Concomitant Procedures form.

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 MAR 2021	COMPLETE METABOLIC PROFILE	Adverse Event	
23 MAR 2021	COMPLETE BLOOD COUNT	Adverse Event	
23 MAR 2021	PROTIME-INR	Adverse Event	
23 MAR 2021	APTT	Adverse Event	
23 MAR 2021	TROPONIN-I	Adverse Event	
23 MAR 2021	MAGNESIUM	Adverse Event	
23 MAR 2021	D-DIMER	Adverse Event	
23 MAR 2021	COVID 19 TEST	Adverse Event	
23 MAR 2021	CHEST XRAY	Adverse Event	
23 MAR 2021	STRESS TEST	Adverse Event	
23 MAR 2021	ECHO CARDIAGRAM	Adverse Event	

US3402420

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:22:36

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ◯

SAE (specify) ◯

Death ◯

Lost To Follow-up ◯

Physician decision (specify) ◯

Pregnancy ◯

Protocol deviation (specify) ◯

Study Terminated By Sponsor ◯

Withdrawal of consent by ◯
participant (specify)

Due to SARS-COV-2 ◯

Other ◯

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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	◯

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

SAEID	USA-US059-2021-MRNA-1273-P30 1000014
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
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)	1

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) **26 Apr 2021 23:51:24**

Generated On: 09 Jun 2021 17:22:36

SAEID	USA-US059-2021-MRNA-1273-P30 1000014
Serious	Yes ⬤ No ⭘
Death	Yes ⭘ No ⬤
Life threatening	Yes ⭘ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⬤ No ⭘
Persistent or significant disability or incapacity	Yes ⭘ No ⬤
Congenital anomaly or birth defect	Yes ⭘ No ⬤
Other medically important event	Yes ⭘ No ⬤
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)	1
Date of submission (Pre-filled from custom function)	20/APR/2021 13:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3402420 (Prod: Meridian Clinical Research, LLC)

US3402420

Form: Participant Creation

Generated On: 09 Jun 2021 17:22:36

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'US3402420'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:49:13

Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:31:28

US3402420

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:18
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:49:14

US3402420

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:31:28

US3402420
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'SCRN'	System	22 Aug 2020 14:31:28

US3402420

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered (b) (6) 1965'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:49:15

US3402420

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '55'	(b) (4), (b) (6)	22 Aug 2020 14:31:52

US3402420
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:22:36
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'YEARS'	System	22 Aug 2020 14:31:52

US3402420

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '55'	System	22 Aug 2020 13:35:06

US3402420

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:31:52

US3402420

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:15
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	22 Aug 2020 14:31:52

US3402420

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '1'	(b) (4), (b) (6)	22 Aug 2020 14:31:52

US3402420

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:31:52

US3402420
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:22:36

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:31:52

US3402420

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:31:52

US3402420

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:31:52

US3402420
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:22:36
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:31:52

US3402420
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:22:36
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:31:52

US3402420

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:31:52

US3402420
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:22:36
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:31:52

US3402420

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:15
User entered '22 Aug 2020'	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:35:06

Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:22:36

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Aug 2020'	System	22 Aug 2020 13:35:06

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2020'	System	22 Aug 2020 13:35:06

US3402420

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:15
User entered 'Amendment 2 (2)'	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:35:06

US3402420

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:15
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:35:06

US3402420

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:15
User entered empty.	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:35:06

US3402420

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:15
User entered empty.	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:35:06

US3402420
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:22:36

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:35:06

US3402420

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:49:14

US3402420

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '1'	System	22 Aug 2020 13:35:20

US3402420

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:22:36

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:15
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:35:20

US3402420

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:22:36

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:32:21

US3402420

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 14:37:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:37:16
Data point term sent to Coder	System	22 Aug 2020 14:36:13
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	22 Aug 2020 14:35:24

US3402420

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '29 Dec 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Aug 2020 14:36:32
User entered 'UN Dec 2019'	(b) (4), (b) (6)	22 Aug 2020 14:35:24

US3402420

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:35:24

US3402420

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:35:24

US3402420

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '29 Dec 2019' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:36:32
User entered 'UN Dec 2019'	(b) (4), (b) (6)	22 Aug 2020 14:35:24

US3402420

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:35:24

US3402420

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Dec 2019'	System	22 Aug 2020 14:35:24

US3402420
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:22:36
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2019'	System	22 Aug 2020 14:35:24

US3402420

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Dec 2019'	System	22 Aug 2020 14:35:24

US3402420
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:22:36

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2019'	System	22 Aug 2020 14:35:24

US3402420

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Vascular therapeutic procedures NEC, PT: Angioplasty, LLT: Angioplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:37:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:37:17
Data point term sent to Coder	System	22 Aug 2020 14:36:14
User entered 'ANGIOPLASTY'	(b) (4), (b) (6)	22 Aug 2020 14:36:12

US3402420

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '29 Dec 2019'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:36:12

US3402420

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:36:12

US3402420

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:36:12

US3402420

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
	(b) (4)	
User entered '29 Dec 2019'	(b) (4), (b) (6)	22 Aug 2020 14:36:12

US3402420

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:36:12

US3402420
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:22:36
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Dec 2019'	System	22 Aug 2020 14:36:12

US3402420

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2019'	System	22 Aug 2020 14:36:12

US3402420

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Dec 2019'	System	22 Aug 2020 14:36:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2019'	System	22 Aug 2020 14:36:12

US3402420

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:38:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:38:17
Data point term sent to Coder	System	22 Aug 2020 14:37:14
User entered 'STENT PLACEMENT'	(b) (4), (b) (6)	22 Aug 2020 14:37:09

US3402420

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '29 Dec 2019'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:37:09

US3402420

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:37:09

US3402420

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:37:09

US3402420

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '29 Dec 2019'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:37:09

US3402420

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:37:09

US3402420

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Dec 2019'	System	22 Aug 2020 14:37:09

US3402420
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:22:36
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2019'	System	22 Aug 2020 14:37:09

US3402420

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Dec 2019'	System	22 Aug 2020 14:37:09

US3402420

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2019'	System	22 Aug 2020 14:37:09

US3402420

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 14:39:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:39:17
Data point term sent to Coder	System	22 Aug 2020 14:38:15
User entered 'CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	22 Aug 2020 14:37:42

US3402420

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '29 Dec 2019'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:37:42

US3402420

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:37:42

US3402420

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:37:42

US3402420

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:37:42

US3402420

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:37:42

US3402420

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Dec 2019'	System	22 Aug 2020 14:37:42

US3402420

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2019'	System	22 Aug 2020 14:37:42

US3402420

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:37:42

US3402420

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:37:42

US3402420
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:22:36
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 14:39:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:39:17
Data point term sent to Coder	System	22 Aug 2020 14:38:15
User entered 'ANXIETY'	(b) (4), (b) (6)	22 Aug 2020 14:38:11

US3402420

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
	(b) (4)	
User entered '01 Jan 2020'	(b) (4), (b) (6)	22 Aug 2020 14:38:11

US3402420

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:38:11

US3402420

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:15
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Aug 2020 14:38:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Aug 2020 14:38:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Aug 2020 14:38:33
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Aug 2020 14:38:11
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:38:11

US3402420

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:38:11

US3402420

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:38:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Jan 2020'	System	22 Aug 2020 14:38:11

US3402420

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2020'	System	22 Aug 2020 14:38:11

US3402420

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:38:11

US3402420
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:22:36
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:38:11

US3402420

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 14:40:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:40:18
Data point term sent to Coder	System	22 Aug 2020 14:39:16
User entered 'INSOMNIA'	(b) (4), (b) (6)	22 Aug 2020 14:39:01

US3402420

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '01 Jan 2020'	(b) (4), (b) (6)	22 Aug 2020 14:39:01

Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:22:36
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:39:01

US3402420

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:39:01

US3402420

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:39:01

US3402420

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:39:01

US3402420

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Jan 2020'	System	22 Aug 2020 14:39:01

US3402420

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2020'	System	22 Aug 2020 14:39:01

US3402420
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:22:36
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:39:01

US3402420

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:39:01

US3402420
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:22:36
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 14:41:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:41:19
Data point term sent to Coder	System	22 Aug 2020 14:40:16
User entered 'CODEINE ALLERGY'	(b) (4), (b) (6)	22 Aug 2020 14:39:27

US3402420

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:39:27

US3402420

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:39:27

US3402420

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:39:27

US3402420

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:39:27

US3402420

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:39:27

US3402420

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Jan 2005'	System	22 Aug 2020 14:39:27

US3402420
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:22:36
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2005'	System	22 Aug 2020 14:39:27

US3402420

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:39:27

US3402420

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:39:27

US3402420

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:41:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:41:19
Data point term sent to Coder	System	22 Aug 2020 14:40:16
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	22 Aug 2020 14:39:47

US3402420

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:39:47

US3402420

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:39:47

US3402420

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:39:47

US3402420

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:39:47

US3402420

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:39:47

US3402420
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Jan 2010'	System	22 Aug 2020 14:39:47

US3402420

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2010'	System	22 Aug 2020 14:39:47

US3402420

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:39:47

US3402420

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:39:47

US3402420

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:41:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:41:19
Data point term sent to Coder	System	22 Aug 2020 14:40:17
User entered 'CONGESTIVE HEART FAILURE'	(b) (4), (b) (6)	22 Aug 2020 14:40:16

US3402420

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '29 Dec 2019'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:40:16

US3402420

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:40:16

US3402420

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:40:16

US3402420

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:40:16

US3402420

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:40:16

US3402420

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Dec 2019'	System	22 Aug 2020 14:40:16

US3402420

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2019'	System	22 Aug 2020 14:40:16

US3402420

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:40:16

US3402420

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:40:16

US3402420

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Cardiac dysrhythmia, unspecified - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	23 Aug 2020 10:23:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 10:23:34
Data point term sent to Coder	System	22 Aug 2020 14:41:17
User entered 'CARDIAC DISRHYTHMIA'	(b) (4), (b) (6)	22 Aug 2020 14:40:59

Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '29 Dec 2019'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:40:59

US3402420

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:40:59

US3402420

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:40:59

US3402420

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:40:59

US3402420

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Dec 2019'	System	22 Aug 2020 14:40:59

US3402420

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2019'	System	22 Aug 2020 14:40:59

US3402420

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:40:59

US3402420

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:40:59

US3402420

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 14:43:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:43:19
Data point term sent to Coder	System	22 Aug 2020 14:42:17
User entered 'GASTROESAPHAGEAL REFLUX DISEASE'	(b) (4), (b) (6)	22 Aug 2020 14:41:27

US3402420
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:22:36
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:41:27

US3402420

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:41:27

US3402420

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:41:27

US3402420

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:41:27

US3402420

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:41:27

US3402420

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Jan 2000'	System	22 Aug 2020 14:41:27

US3402420
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:22:36
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2000'	System	22 Aug 2020 14:41:27

US3402420
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:22:36
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:41:27

US3402420

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered empty.	System	22 Aug 2020 14:41:27

US3402420

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Vascular therapeutic procedures NEC, PT: Angioplasty, LLT: Angioplasty - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 14:43:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:43:19
Data point term sent to Coder	System	22 Aug 2020 14:42:17
User entered 'ANGIOPLASTY'	(b) (4), (b) (6)	22 Aug 2020 14:42:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '28 Jan 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:42:15

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:42:15

US3402420

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:42:15

US3402420

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
	(b) (4)	
User entered '28 Jan 2020'	(b) (4), (b) (6)	22 Aug 2020 14:42:15

US3402420

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:42:15

US3402420

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Jan 2020'	System	22 Aug 2020 14:42:15

US3402420

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2020'	System	22 Aug 2020 14:42:15

US3402420

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Jan 2020'	System	22 Aug 2020 14:42:15

US3402420

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2020'	System	22 Aug 2020 14:42:15

US3402420

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:44:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:44:23
Data point term sent to Coder	System	22 Aug 2020 14:43:18
User entered 'STENT PLACEMENT'	(b) (4), (b) (6)	22 Aug 2020 14:42:50

US3402420

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '28 Jan 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:42:50

US3402420

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:42:50

US3402420

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:22:36

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:42:50

US3402420

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
	(b) (4)	
User entered '28 Jan 2020'	(b) (4), (b) (6)	22 Aug 2020 14:42:50

US3402420

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:42:50

US3402420

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Jan 2020'	System	22 Aug 2020 14:42:50

US3402420
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 17:22:36
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2020'	System	22 Aug 2020 14:42:50

US3402420

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:22:36

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'Jan 2020'	System	22 Aug 2020 14:42:50

US3402420
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 17:22:36
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '2020'	System	22 Aug 2020 14:42:50

US3402420

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:18
User entered 'Yes (Y)'	(b) (4)	22 Aug 2020 14:33:35
	(b) (4), (b) (6)	

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:18
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:33:35

US3402420

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:18
User entered '08:30'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:33:35

US3402420

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered '22 Aug 2020 08:30'	System	22 Aug 2020 14:33:35

US3402420
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:18
User entered '176' cm	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:33:35
DataPoint set to visible.	System	22 Aug 2020 13:35:20

US3402420

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:18
User entered '95.2' kg	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:33:35
DataPoint set to visible.	System	22 Aug 2020 13:35:20

US3402420

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
Amendment Manager: User entered '30.73347'	System	17 Sep 2020 00:19:45
User entered '30.7'	System	22 Aug 2020 14:33:35
DataPoint set to visible.	System	22 Aug 2020 13:35:20

US3402420
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'kg/m2'	System	22 Aug 2020 14:33:35
DataPoint set to visible.	System	22 Aug 2020 13:35:20

US3402420

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 20:13:57
User entered '36.3' C	(b) (4), (b) (6)	22 Aug 2020 14:33:35

US3402420

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:18
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 20:13:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Aug 2020 14:33:35

US3402420
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:18
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:33:35

US3402420

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 20:13:57
User entered '58'	(b) (4), (b) (6)	22 Aug 2020 14:33:35

US3402420
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'bpm'	System	22 Aug 2020 14:33:35

US3402420
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 20:13:57
User entered '14'	(b) (4), (b) (6)	22 Aug 2020 14:33:35

Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'breaths/min'	System	22 Aug 2020 14:33:35

US3402420

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 20:13:57
User entered '108'	(b) (4), (b) (6)	22 Aug 2020 14:33:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'mmHg'	System	22 Aug 2020 14:33:35

FDA-CBER-2022-1614-1771464

US3402420

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:18
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 20:13:57
	(b) (4)	
User entered '60'	(b) (4), (b) (6)	22 Aug 2020 14:33:35

US3402420

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User entered 'mmHg'	System	22 Aug 2020 14:33:35

US3402420
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46

US3402420

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:43:14

US3402420

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 14:43:14

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered 'IN PUBLIC OVER THREE TIMES PER WEEK'	(b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '1'	(b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:01:46
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:15
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:44:21

US3402420

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:33:36

US3402420
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '22 Aug 2020'	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:33:36

US3402420

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Clinic (Clinic)'	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:33:36

US3402420
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'VISIT1'	System	22 Aug 2020 13:33:36

US3402420

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '22 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:54:13

US3402420

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '144744'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:54:13

US3402420

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:54:13

US3402420

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:45:23

US3402420

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:45:23

US3402420

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:45:23

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:45:23

FDA-CBER-2022-1614-1771502

US3402420

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:45:23

US3402420

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:14:59
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	03 Nov 2020 15:22:58
User entered 'No (N)'	Tammy Kohn (b) (4)	03 Nov 2020 15:22:52
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 12:18:58
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:05
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:17:06

US3402420
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:22:36
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 20:14:14
User entered '176' cm	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 20:14:14
User entered '95.2' kg	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:22:36
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	20 Dec 2020 20:14:14
	(b) (4)	
User entered '176' cm	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:22:36
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 20:14:14
User entered '95.2' kg	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:47:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '08:30'	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '22 Aug 2020 08:30'	System	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '36.3' C	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:47:25

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '58'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'bpm'	System	22 Aug 2020 14:47:25

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '14'	(b) (4), (b) (6)	22 Aug 2020 14:47:25

FDA-CBER-2022-1614-1771519

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'breaths/min'	System	22 Aug 2020 14:47:25

FDA-CBER-2022-1614-1771520

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '108'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'mmHg'	System	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '60'	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'mmHg'	System	22 Aug 2020 14:47:25

US3402420
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:22:36
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 20:14:14
User entered '176' cm	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:22:36
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 20:14:14
User entered '95.2' kg	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '09:54'	(b) (4), (b) (6)	22 Aug 2020 14:47:25

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '22 Aug 2020 09:54'	System	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '36.0' C	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:47:25

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '54'	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:22:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'bpm'	System	22 Aug 2020 14:47:25

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '14'	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'breaths/min'	System	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '106'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'mmHg'	System	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '64'	(b) (4), (b) (6)	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'mmHg'	System	22 Aug 2020 14:47:25

US3402420

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:47:35

US3402420

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:47:35

US3402420

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:36:31

US3402420

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:36:31

US3402420

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:36:31

US3402420
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:22:36
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'MRNA-1273 OR PLACEBO'	System	22 Aug 2020 13:36:31

US3402420

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '22 Aug 2020'	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:36:31

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:22:36

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '09:23'	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:36:31

US3402420

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '22 Aug 2020 09:23'	System	22 Aug 2020 13:36:31

US3402420

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Left Arm (LEFT ARM)'	Abigail Wine (b) (4) (b) (4)	22 Aug 2020 13:36:31

US3402420

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'ONCE'	System	22 Aug 2020 13:36:31

US3402420

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'INTRAMUSCULAR'	System	22 Aug 2020 13:36:31

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:48:03

US3402420

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:48:03

US3402420

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '09:09'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:48:03

US3402420

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '22 Aug 2020 09:09'	System	22 Aug 2020 14:48:03

US3402420

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:22:36

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	22 Aug 2020 14:48:40
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	22 Aug 2020 14:48:40
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Aug 2020 14:48:40
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	22 Aug 2020 14:48:22
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:48:22

US3402420

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Aug 2020 14:48:22

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:48:22

US3402420

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered '08:45'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:48:22

US3402420

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '22 Aug 2020 08:45'	System	22 Aug 2020 14:48:40
User entered empty.	System	22 Aug 2020 14:48:22

US3402420

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Aug 2020 14:48:22

US3402420

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:48:22

US3402420

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:48:22

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered empty.	System	22 Aug 2020 14:48:22

US3402420

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:48:46

US3402420

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '1'	System	22 Aug 2020 14:48:46

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:53:41', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b2edcfe3-10f8-448a-87c4-6268ad4830a3'	System	22 Aug 2020 13:55:37
User entered 'Yes (Y)'	System	22 Aug 2020 13:55:37

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:55:18', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b2edcfe3-10f8-448a-87c4-6268ad4830a3'	System	22 Aug 2020 13:55:37
User entered '96.8'	System	22 Aug 2020 13:55:37

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:55:26', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b2edcfe3-10f8-448a-87c4-6268ad4830a3'	System	22 Aug 2020 13:55:37
User entered 'No (N)'	System	22 Aug 2020 13:55:37

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:55:33', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b2edcfe3-10f8-448a-87c4-6268ad4830a3'	System	22 Aug 2020 13:55:37
User entered '22 Aug 2020 09:55'	System	22 Aug 2020 13:55:37

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '22 Aug 2020 09:43'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '22 Aug 2020 12:13'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T18:59:14', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '37e5b91b-fc79-40a2-a67a-5e692abcbe40'	System	22 Aug 2020 22:59:32
User entered 'Yes (Y)'	System	22 Aug 2020 22:59:32

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T18:59:20', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '37e5b91b-fc79-40a2-a67a-5e692abcbe40'	System	22 Aug 2020 22:59:32
User entered '98.0'	System	22 Aug 2020 22:59:32

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T18:59:24', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '37e5b91b-fc79-40a2-a67a-5e692abcbe40'	System	22 Aug 2020 22:59:32
User entered 'No (N)'	System	22 Aug 2020 22:59:32

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T18:59:31', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '37e5b91b-fc79-40a2-a67a-5e692abcbe40'	System	22 Aug 2020 22:59:32
User entered '22 Aug 2020 18:59'	System	22 Aug 2020 22:59:32

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '22 Aug 2020 13:08'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 2'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:24:54', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5383ef36-2225-48bb-b49c-109a1eae05db'	System	23 Aug 2020 17:25:11
User entered 'Yes (Y)'	System	23 Aug 2020 17:25:11

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:24:59', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5383ef36-2225-48bb-b49c-109a1eae05db'	System	23 Aug 2020 17:25:11
User entered '97.8'	System	23 Aug 2020 17:25:11

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:25:02', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5383ef36-2225-48bb-b49c-109a1eae05db'	System	23 Aug 2020 17:25:11
User entered 'No (N)'	System	23 Aug 2020 17:25:11

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:25:07', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5383ef36-2225-48bb-b49c-109a1eae05db'	System	23 Aug 2020 17:25:11
User entered '23 Aug 2020 13:25'	System	23 Aug 2020 17:25:11

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 3'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:03:42', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8e911f61-4cd4-454a-974c-4ada5862af6f'	System	24 Aug 2020 20:04:37
User entered 'Yes (Y)'	System	24 Aug 2020 20:04:37

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:04:27', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8e911f61-4cd4-454a-974c-4ada5862af6f'	System	24 Aug 2020 20:04:37
User entered '97.6'	System	24 Aug 2020 20:04:37

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:04:30', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8e911f61-4cd4-454a-974c-4ada5862af6f'	System	24 Aug 2020 20:04:37
User entered 'No (N)'	System	24 Aug 2020 20:04:37

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:04:34', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8e911f61-4cd4-454a-974c-4ada5862af6f'	System	24 Aug 2020 20:04:37
User entered '24 Aug 2020 16:04'	System	24 Aug 2020 20:04:37

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:22:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 4'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:16:12', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '872ed320-3423-420b-969d-b730a1c5bf94'	System	25 Aug 2020 21:16:36
User entered 'Yes (Y)'	System	25 Aug 2020 21:16:36

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:16:22', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '872ed320-3423-420b-969d-b730a1c5bf94'	System	25 Aug 2020 21:16:36
User entered '97.0'	System	25 Aug 2020 21:16:36

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:16:29', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '872ed320-3423-420b-969d-b730a1c5bf94'	System	25 Aug 2020 21:16:36
User entered 'No (N)'	System	25 Aug 2020 21:16:36

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:16:33', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '872ed320-3423-420b-969d-b730a1c5bf94'	System	25 Aug 2020 21:16:36
User entered '25 Aug 2020 17:16'	System	25 Aug 2020 21:16:36

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 5'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:34:35', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '6c78e40a-2ce4-4378-88dd-5c67f40c189b'	System	26 Aug 2020 20:34:51
User entered 'Yes (Y)'	System	26 Aug 2020 20:34:51

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:34:42', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '6c78e40a-2ce4-4378-88dd-5c67f40c189b'	System	26 Aug 2020 20:34:51
User entered '96.4'	System	26 Aug 2020 20:34:51

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:34:46', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '6c78e40a-2ce4-4378-88dd-5c67f40c189b'	System	26 Aug 2020 20:34:51
User entered 'No (N)'	System	26 Aug 2020 20:34:51

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:34:48', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '6c78e40a-2ce4-4378-88dd-5c67f40c189b'	System	26 Aug 2020 20:34:51
User entered '26 Aug 2020 16:34'	System	26 Aug 2020 20:34:51

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 6'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:07:54', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5bdfb46e-9b6d-4c82-86b1-5199457a0e00'	System	28 Aug 2020 02:08:08
User entered 'Yes (Y)'	System	28 Aug 2020 02:08:08

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:07:58', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5bdfb46e-9b6d-4c82-86b1-5199457a0e00'	System	28 Aug 2020 02:08:08
User entered '97.0'	System	28 Aug 2020 02:08:08

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:02', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5bdfb46e-9b6d-4c82-86b1-5199457a0e00'	System	28 Aug 2020 02:08:08
User entered 'No (N)'	System	28 Aug 2020 02:08:08

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:04', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5bdfb46e-9b6d-4c82-86b1-5199457a0e00'	System	28 Aug 2020 02:08:08
User entered '27 Aug 2020 22:08'	System	28 Aug 2020 02:08:08

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:22:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 7'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:30:25', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8efd493c-b368-4dba-ad26-da7046b454b0'	System	28 Aug 2020 18:30:46
User entered 'Yes (Y)'	System	28 Aug 2020 18:30:46

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:30:33', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8efd493c-b368-4dba-ad26-da7046b454b0'	System	28 Aug 2020 18:30:46
User entered '96.5'	System	28 Aug 2020 18:30:46

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:30:38', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8efd493c-b368-4dba-ad26-da7046b454b0'	System	28 Aug 2020 18:30:46
User entered 'No (N)'	System	28 Aug 2020 18:30:46

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:30:42', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8efd493c-b368-4dba-ad26-da7046b454b0'	System	28 Aug 2020 18:30:46
User entered '28 Aug 2020 14:30'	System	28 Aug 2020 18:30:46

US3402420
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:22:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:55:53', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'db10c9ee-777a-4f83-8837-37f524808d45'	System	22 Aug 2020 13:56:26
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 13:56:26

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:56:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'db10c9ee-777a-4f83-8837-37f524808d45'	System	22 Aug 2020 13:56:26
User entered 'No (N)'	System	22 Aug 2020 13:56:26

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:56:08', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'db10c9ee-777a-4f83-8837-37f524808d45'	System	22 Aug 2020 13:56:26
User entered 'No (N)'	System	22 Aug 2020 13:56:26

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:56:19', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'db10c9ee-777a-4f83-8837-37f524808d45'	System	22 Aug 2020 13:56:26
User entered 'None (1)'	System	22 Aug 2020 13:56:26

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:56:22', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'db10c9ee-777a-4f83-8837-37f524808d45'	System	22 Aug 2020 13:56:26
User entered '22 Aug 2020 09:56'	System	22 Aug 2020 13:56:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '22 Aug 2020 09:43'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '22 Aug 2020 12:13'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T18:59:39', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'edd3d22d-e986-468f-9be0-87b8f4389f21'	System	22 Aug 2020 22:59:59
User entered 'None (1)'	System	22 Aug 2020 22:59:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T18:59:43', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'edd3d22d-e986-468f-9be0-87b8f4389f21'	System	22 Aug 2020 22:59:59
User entered 'No (N)'	System	22 Aug 2020 22:59:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T18:59:46', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'edd3d22d-e986-468f-9be0-87b8f4389f21'	System	22 Aug 2020 22:59:59
User entered 'No (N)'	System	22 Aug 2020 22:59:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T18:59:51', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'edd3d22d-e986-468f-9be0-87b8f4389f21'	System	22 Aug 2020 22:59:59
User entered 'None (1)'	System	22 Aug 2020 22:59:59

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T18:59:57', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'edd3d22d-e986-468f-9be0-87b8f4389f21'	System	22 Aug 2020 22:59:59
User entered '22 Aug 2020 18:59'	System	22 Aug 2020 22:59:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '22 Aug 2020 13:08'	System	22 Aug 2020 13:36:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 2'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:25:17', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b2b0ebd5-0014-4257-a2ac-f3a9da1027f8'	System	23 Aug 2020 17:25:55
User entered 'None (1)'	System	23 Aug 2020 17:25:55

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:25:29', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b2b0ebd5-0014-4257-a2ac-f3a9da1027f8'	System	23 Aug 2020 17:25:55
User entered 'No (N)'	System	23 Aug 2020 17:25:55

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:25:33', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b2b0ebd5-0014-4257-a2ac-f3a9da1027f8'	System	23 Aug 2020 17:25:55
User entered 'No (N)'	System	23 Aug 2020 17:25:55

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:25:39', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b2b0ebd5-0014-4257-a2ac-f3a9da1027f8'	System	23 Aug 2020 17:25:55
User entered 'None (1)'	System	23 Aug 2020 17:25:55

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:25:52', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b2b0ebd5-0014-4257-a2ac-f3a9da1027f8'	System	23 Aug 2020 17:25:55
User entered '23 Aug 2020 13:25'	System	23 Aug 2020 17:25:55

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:22:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 3'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:04:39', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'f6e09cb2-dcb3-4ef2-ac48-11a624489309'	System	24 Aug 2020 20:04:59
User entered 'None (1)'	System	24 Aug 2020 20:04:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:04:41', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'f6e09cb2-dcb3-4ef2-ac48-11a624489309'	System	24 Aug 2020 20:04:59
User entered 'No (N)'	System	24 Aug 2020 20:04:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:04:45', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'f6e09cb2-dcb3-4ef2-ac48-11a624489309'	System	24 Aug 2020 20:04:59
User entered 'No (N)'	System	24 Aug 2020 20:04:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:04:49', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'f6e09cb2-dcb3-4ef2-ac48-11a624489309'	System	24 Aug 2020 20:04:59
User entered 'None (1)'	System	24 Aug 2020 20:04:59

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:04:54', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'f6e09cb2-dcb3-4ef2-ac48-11a624489309'	System	24 Aug 2020 20:04:59
User entered '24 Aug 2020 16:04'	System	24 Aug 2020 20:04:59

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:22:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 4'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:16:50', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'e1b7ed9d-f442-4101-afa8-abe6d324b151'	System	25 Aug 2020 21:17:05
User entered 'None (1)'	System	25 Aug 2020 21:17:05

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:16:53', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'e1b7ed9d-f442-4101-afa8-abe6d324b151'	System	25 Aug 2020 21:17:05
User entered 'No (N)'	System	25 Aug 2020 21:17:05

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:16:57', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'e1b7ed9d-f442-4101-afa8-abe6d324b151'	System	25 Aug 2020 21:17:05
User entered 'No (N)'	System	25 Aug 2020 21:17:05

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:16:59', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'e1b7ed9d-f442-4101-afa8-abe6d324b151'	System	25 Aug 2020 21:17:05
User entered 'None (1)'	System	25 Aug 2020 21:17:05

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:17:02', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'e1b7ed9d-f442-4101-afa8-abe6d324b151'	System	25 Aug 2020 21:17:05
User entered '25 Aug 2020 17:17'	System	25 Aug 2020 21:17:05

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 5'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:34:53', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0248f780-27ab-4e32-8896-cad6c9c3e33e'	System	26 Aug 2020 20:35:08
User entered 'None (1)'	System	26 Aug 2020 20:35:08

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:34:57', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0248f780-27ab-4e32-8896-cad6c9c3e33e'	System	26 Aug 2020 20:35:08
User entered 'No (N)'	System	26 Aug 2020 20:35:08

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:35:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0248f780-27ab-4e32-8896-cad6c9c3e33e'	System	26 Aug 2020 20:35:08
User entered 'No (N)'	System	26 Aug 2020 20:35:08

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:35:03', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0248f780-27ab-4e32-8896-cad6c9c3e33e'	System	26 Aug 2020 20:35:08
User entered 'None (1)'	System	26 Aug 2020 20:35:08

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:35:05', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0248f780-27ab-4e32-8896-cad6c9c3e33e'	System	26 Aug 2020 20:35:08
User entered '26 Aug 2020 16:35'	System	26 Aug 2020 20:35:08

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:22:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:22:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 6'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:08', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'e5431086-80e9-4cd3-8b39-8920d01686b4'	System	28 Aug 2020 02:08:24
User entered 'None (1)'	System	28 Aug 2020 02:08:24

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:11', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'e5431086-80e9-4cd3-8b39-8920d01686b4'	System	28 Aug 2020 02:08:24
User entered 'No (N)'	System	28 Aug 2020 02:08:24

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:14', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'e5431086-80e9-4cd3-8b39-8920d01686b4'	System	28 Aug 2020 02:08:24
User entered 'No (N)'	System	28 Aug 2020 02:08:24

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:17', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'e5431086-80e9-4cd3-8b39-8920d01686b4'	System	28 Aug 2020 02:08:24
User entered 'None (1)'	System	28 Aug 2020 02:08:24

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:19', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'e5431086-80e9-4cd3-8b39-8920d01686b4'	System	28 Aug 2020 02:08:24
User entered '27 Aug 2020 22:08'	System	28 Aug 2020 02:08:24

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:22:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 7'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:30:47', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '3edf2f53-75a9-45e2-9fdc-c1c3d5dffb54'	System	28 Aug 2020 18:31:00
User entered 'None (1)'	System	28 Aug 2020 18:31:00

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:30:49', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '3edf2f53-75a9-45e2-9fdc-c1c3d5dffb54'	System	28 Aug 2020 18:31:00
User entered 'No (N)'	System	28 Aug 2020 18:31:00

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:30:52', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '3edf2f53-75a9-45e2-9fdc-c1c3d5dffb54'	System	28 Aug 2020 18:31:00
User entered 'No (N)'	System	28 Aug 2020 18:31:00

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:30:56', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '3edf2f53-75a9-45e2-9fdc-c1c3d5dffb54'	System	28 Aug 2020 18:31:00
User entered 'None (1)'	System	28 Aug 2020 18:31:00

US3402420
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:30:59', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '3edf2f53-75a9-45e2-9fdc-c1c3d5dffb54'	System	28 Aug 2020 18:31:00
User entered '28 Aug 2020 14:30'	System	28 Aug 2020 18:31:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:56:32', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1a8426b1-3b69-45ec-8658-05f895513632'	System	22 Aug 2020 13:56:58
User entered 'None (0)'	System	22 Aug 2020 13:56:58

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:56:35', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1a8426b1-3b69-45ec-8658-05f895513632'	System	22 Aug 2020 13:56:58
User entered 'None (0)'	System	22 Aug 2020 13:56:58

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:56:39', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1a8426b1-3b69-45ec-8658-05f895513632'	System	22 Aug 2020 13:56:58
User entered 'None (0)'	System	22 Aug 2020 13:56:58

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:56:41', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1a8426b1-3b69-45ec-8658-05f895513632'	System	22 Aug 2020 13:56:58
User entered 'None (0)'	System	22 Aug 2020 13:56:58

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:56:44', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1a8426b1-3b69-45ec-8658-05f895513632'	System	22 Aug 2020 13:56:58
User entered 'None (0)'	System	22 Aug 2020 13:56:58

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:56:47', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1a8426b1-3b69-45ec-8658-05f895513632'	System	22 Aug 2020 13:56:58
User entered 'None (0)'	System	22 Aug 2020 13:56:58

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:56:54', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1a8426b1-3b69-45ec-8658-05f895513632'	System	22 Aug 2020 13:56:58
User entered 'No (N)'	System	22 Aug 2020 13:56:58

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T09:56:57', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1a8426b1-3b69-45ec-8658-05f895513632'	System	22 Aug 2020 13:56:58
User entered '22 Aug 2020 09:56'	System	22 Aug 2020 13:56:58

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '22 Aug 2020 09:43'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '22 Aug 2020 12:13'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T19:00:03', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'a6670351-53bf-4632-9e83-4797efdead23'	System	22 Aug 2020 23:00:26
User entered 'None (0)'	System	22 Aug 2020 23:00:26

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T19:00:05', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'a6670351-53bf-4632-9e83-4797efdead23'	System	22 Aug 2020 23:00:26
User entered 'None (0)'	System	22 Aug 2020 23:00:26

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T19:00:08', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'a6670351-53bf-4632-9e83-4797efdead23'	System	22 Aug 2020 23:00:26
User entered 'None (0)'	System	22 Aug 2020 23:00:26

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T19:00:11', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'a6670351-53bf-4632-9e83-4797efdead23'	System	22 Aug 2020 23:00:26
User entered 'None (0)'	System	22 Aug 2020 23:00:26

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T19:00:13', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'a6670351-53bf-4632-9e83-4797efdead23'	System	22 Aug 2020 23:00:26
User entered 'None (0)'	System	22 Aug 2020 23:00:26

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T19:00:15', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'a6670351-53bf-4632-9e83-4797efdead23'	System	22 Aug 2020 23:00:26
User entered 'None (0)'	System	22 Aug 2020 23:00:26

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T19:00:22', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'a6670351-53bf-4632-9e83-4797efdead23'	System	22 Aug 2020 23:00:26
User entered 'No (N)'	System	22 Aug 2020 23:00:26

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-22T19:00:24', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'a6670351-53bf-4632-9e83-4797efdead23'	System	22 Aug 2020 23:00:26
User entered '22 Aug 2020 19:00'	System	22 Aug 2020 23:00:26

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '22 Aug 2020 13:08'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 2'	System	22 Aug 2020 13:36:31

FDA-CBER-2022-1614-1771712

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:25:58', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b519e88b-bb7c-4287-83aa-e29c548a45aa'	System	23 Aug 2020 17:26:24
User entered 'None (0)'	System	23 Aug 2020 17:26:24

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:26:01', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b519e88b-bb7c-4287-83aa-e29c548a45aa'	System	23 Aug 2020 17:26:24
User entered 'None (0)'	System	23 Aug 2020 17:26:24

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:26:03', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b519e88b-bb7c-4287-83aa-e29c548a45aa'	System	23 Aug 2020 17:26:24
User entered 'None (0)'	System	23 Aug 2020 17:26:24

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:26:06', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b519e88b-bb7c-4287-83aa-e29c548a45aa'	System	23 Aug 2020 17:26:24
User entered 'None (0)'	System	23 Aug 2020 17:26:24

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:26:09', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b519e88b-bb7c-4287-83aa-e29c548a45aa'	System	23 Aug 2020 17:26:24
User entered 'None (0)'	System	23 Aug 2020 17:26:24

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:26:11', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b519e88b-bb7c-4287-83aa-e29c548a45aa'	System	23 Aug 2020 17:26:24
User entered 'None (0)'	System	23 Aug 2020 17:26:24

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:26:19', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b519e88b-bb7c-4287-83aa-e29c548a45aa'	System	23 Aug 2020 17:26:24
User entered 'No (N)'	System	23 Aug 2020 17:26:24

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-23T13:26:22', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b519e88b-bb7c-4287-83aa-e29c548a45aa'	System	23 Aug 2020 17:26:24
User entered '23 Aug 2020 13:26'	System	23 Aug 2020 17:26:24

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 3'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:22:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:04:59', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '9bde82be-cc57-422d-8b19-cad780d3c731'	System	24 Aug 2020 20:05:19
User entered 'None (0)'	System	24 Aug 2020 20:05:19

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:05:01', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '9bde82be-cc57-422d-8b19-cad780d3c731'	System	24 Aug 2020 20:05:19
User entered 'None (0)'	System	24 Aug 2020 20:05:19

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:05:04', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '9bde82be-cc57-422d-8b19-cad780d3c731'	System	24 Aug 2020 20:05:19
User entered 'None (0)'	System	24 Aug 2020 20:05:19

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:05:08', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '9bde82be-cc57-422d-8b19-cad780d3c731'	System	24 Aug 2020 20:05:19
User entered 'None (0)'	System	24 Aug 2020 20:05:19

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:05:11', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '9bde82be-cc57-422d-8b19-cad780d3c731'	System	24 Aug 2020 20:05:19
User entered 'None (0)'	System	24 Aug 2020 20:05:19

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:05:13', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '9bde82be-cc57-422d-8b19-cad780d3c731'	System	24 Aug 2020 20:05:19
User entered 'None (0)'	System	24 Aug 2020 20:05:19

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:05:15', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '9bde82be-cc57-422d-8b19-cad780d3c731'	System	24 Aug 2020 20:05:19
User entered 'No (N)'	System	24 Aug 2020 20:05:19

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-24T16:05:18', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '9bde82be-cc57-422d-8b19-cad780d3c731'	System	24 Aug 2020 20:05:19
User entered '24 Aug 2020 16:05'	System	24 Aug 2020 20:05:19

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 4'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:17:11', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b1b7189e-9363-4302-ab0f-fc09d8f7de32'	System	25 Aug 2020 21:17:31
User entered 'No interference with activity (1)'	System	25 Aug 2020 21:17:31

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:17:14', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b1b7189e-9363-4302-ab0f-fc09d8f7de32'	System	25 Aug 2020 21:17:31
User entered 'None (0)'	System	25 Aug 2020 21:17:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:17:16', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b1b7189e-9363-4302-ab0f-fc09d8f7de32'	System	25 Aug 2020 21:17:31
User entered 'None (0)'	System	25 Aug 2020 21:17:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:17:19', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b1b7189e-9363-4302-ab0f-fc09d8f7de32'	System	25 Aug 2020 21:17:31
User entered 'None (0)'	System	25 Aug 2020 21:17:31

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:22:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:17:21', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b1b7189e-9363-4302-ab0f-fc09d8f7de32'	System	25 Aug 2020 21:17:31
User entered 'None (0)'	System	25 Aug 2020 21:17:31

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:22:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:17:23', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b1b7189e-9363-4302-ab0f-fc09d8f7de32'	System	25 Aug 2020 21:17:31
User entered 'None (0)'	System	25 Aug 2020 21:17:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:17:26', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b1b7189e-9363-4302-ab0f-fc09d8f7de32'	System	25 Aug 2020 21:17:31
User entered 'No (N)'	System	25 Aug 2020 21:17:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-25T17:17:29', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b1b7189e-9363-4302-ab0f-fc09d8f7de32'	System	25 Aug 2020 21:17:31
User entered '25 Aug 2020 17:17'	System	25 Aug 2020 21:17:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 5'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:35:10', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '063482be-040a-4126-8793-cf59d6e1e0aa'	System	26 Aug 2020 20:35:36
User entered 'No interference with activity (1)'	System	26 Aug 2020 20:35:36

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:35:14', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '063482be-040a-4126-8793-cf59d6e1e0aa'	System	26 Aug 2020 20:35:36
User entered 'None (0)'	System	26 Aug 2020 20:35:36

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:35:17', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '063482be-040a-4126-8793-cf59d6e1e0aa'	System	26 Aug 2020 20:35:36
User entered 'None (0)'	System	26 Aug 2020 20:35:36

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:35:19', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '063482be-040a-4126-8793-cf59d6e1e0aa'	System	26 Aug 2020 20:35:36
User entered 'None (0)'	System	26 Aug 2020 20:35:36

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:35:22', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '063482be-040a-4126-8793-cf59d6e1e0aa'	System	26 Aug 2020 20:35:36
User entered 'None (0)'	System	26 Aug 2020 20:35:36

FDA-CBER-2022-1614-1771750

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:35:24', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '063482be-040a-4126-8793-cf59d6e1e0aa'	System	26 Aug 2020 20:35:36
User entered 'None (0)'	System	26 Aug 2020 20:35:36

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:35:28', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '063482be-040a-4126-8793-cf59d6e1e0aa'	System	26 Aug 2020 20:35:36
User entered 'No (N)'	System	26 Aug 2020 20:35:36

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-26T16:35:32', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '063482be-040a-4126-8793-cf59d6e1e0aa'	System	26 Aug 2020 20:35:36
User entered '26 Aug 2020 16:35'	System	26 Aug 2020 20:35:36

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 6'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:23', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '345a83b6-82ad-4363-b4ab-c996225263a2'	System	28 Aug 2020 02:08:44
User entered 'None (0)'	System	28 Aug 2020 02:08:44

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:25', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '345a83b6-82ad-4363-b4ab-c996225263a2'	System	28 Aug 2020 02:08:44
User entered 'None (0)'	System	28 Aug 2020 02:08:44

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:27', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '345a83b6-82ad-4363-b4ab-c996225263a2'	System	28 Aug 2020 02:08:44
User entered 'None (0)'	System	28 Aug 2020 02:08:44

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:29', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '345a83b6-82ad-4363-b4ab-c996225263a2'	System	28 Aug 2020 02:08:44
User entered 'None (0)'	System	28 Aug 2020 02:08:44

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:31', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '345a83b6-82ad-4363-b4ab-c996225263a2'	System	28 Aug 2020 02:08:44
User entered 'None (0)'	System	28 Aug 2020 02:08:44

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:33', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '345a83b6-82ad-4363-b4ab-c996225263a2'	System	28 Aug 2020 02:08:44
User entered 'None (0)'	System	28 Aug 2020 02:08:44

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:36', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '345a83b6-82ad-4363-b4ab-c996225263a2'	System	28 Aug 2020 02:08:44
User entered 'No (N)'	System	28 Aug 2020 02:08:44

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-27T22:08:42', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '345a83b6-82ad-4363-b4ab-c996225263a2'	System	28 Aug 2020 02:08:44
User entered '27 Aug 2020 22:08'	System	28 Aug 2020 02:08:44

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

FDA-CBER-2022-1614-1771766

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 7'	System	22 Aug 2020 13:36:31

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:22:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:31:02', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '189018e5-fc72-469e-b801-0904443a1184'	System	28 Aug 2020 18:31:26
User entered 'None (0)'	System	28 Aug 2020 18:31:26

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:31:04', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '189018e5-fc72-469e-b801-0904443a1184'	System	28 Aug 2020 18:31:26
User entered 'None (0)'	System	28 Aug 2020 18:31:26

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:22:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:31:06', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '189018e5-fc72-469e-b801-0904443a1184'	System	28 Aug 2020 18:31:26
User entered 'None (0)'	System	28 Aug 2020 18:31:26

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:31:08', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '189018e5-fc72-469e-b801-0904443a1184'	System	28 Aug 2020 18:31:26
User entered 'None (0)'	System	28 Aug 2020 18:31:26

US3402420
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:22:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:31:10', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '189018e5-fc72-469e-b801-0904443a1184'	System	28 Aug 2020 18:31:26
User entered 'None (0)'	System	28 Aug 2020 18:31:26

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:31:13', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '189018e5-fc72-469e-b801-0904443a1184'	System	28 Aug 2020 18:31:26
User entered 'None (0)'	System	28 Aug 2020 18:31:26

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:31:22', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '189018e5-fc72-469e-b801-0904443a1184'	System	28 Aug 2020 18:31:26
User entered 'No (N)'	System	28 Aug 2020 18:31:26

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-08-28T14:31:24', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '189018e5-fc72-469e-b801-0904443a1184'	System	28 Aug 2020 18:31:26
User entered '28 Aug 2020 14:31'	System	28 Aug 2020 18:31:26

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 13:36:31

US3402420

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 13:36:31

US3402420

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 11:31:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '29 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 11:31:46

US3402420

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 11:31:46

US3402420

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Aug 2020 11:31:46

US3402420

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 11:31:52

US3402420
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '1'	System	31 Aug 2020 11:31:52

US3402420

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 12:02:21

US3402420

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '8 Sep 2020'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 12:02:21

US3402420

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 12:02:21

US3402420

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Sep 2020 12:02:21

US3402420
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 12:02:25

US3402420
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '1'	System	16 Sep 2020 12:02:25

US3402420
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 12:02:44

US3402420

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '12 Sep 2020'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 12:02:44

US3402420

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 12:02:44

US3402420

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Sep 2020 12:02:44

US3402420

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 12:02:49

US3402420
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '1'	System	16 Sep 2020 12:02:49

US3402420

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:49:02

US3402420

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '23 Sep 2020'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:49:02

US3402420

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:49:02

US3402420
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'VISIT2'	System	23 Sep 2020 12:49:02

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '23 Sep 2020'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '07:36'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '23 Sep 2020 07:36'	System	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '36.6' C	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '62'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'bpm'	System	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '13'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'breaths/min'	System	23 Sep 2020 12:50:24

FDA-CBER-2022-1614-1771811

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '110'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'mmHg'	System	23 Sep 2020 12:50:24

FDA-CBER-2022-1614-1771813

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '70'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'mmHg'	System	23 Sep 2020 12:50:24

FDA-CBER-2022-1614-1771815

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:27:51
	(b) (4)	
User entered '23 Sep 2020'	Traci Hull (b) (4)	23 Sep 2020 12:50:24
	(b) (4)	

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '08:41'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '23 Sep 2020 08:41'	System	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '36.6' C	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:22:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '57'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'bpm'	System	23 Sep 2020 12:50:24

FDA-CBER-2022-1614-1771825

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '14'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'breaths/min'	System	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '108'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

US3402420

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'mmHg'	System	23 Sep 2020 12:50:24

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '74'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'mmHg'	System	23 Sep 2020 12:50:24

FDA-CBER-2022-1614-1771831

US3402420

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:30

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '23 Sep 2020'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:30

US3402420

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	23 Sep 2020 12:18:29

US3402420

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Abigail Wine (b) (4) (b) (4)	23 Sep 2020 12:18:29

US3402420

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Abigail Wine (b) (4) (b) (4)	23 Sep 2020 12:18:29

US3402420

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 12:18:29

US3402420

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '23 Sep 2020'	Abigail Wine (b) (4) (b) (4)	23 Sep 2020 12:18:29

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '08:10'	Abigail Wine (b) (4) (b) (4)	23 Sep 2020 12:18:29

US3402420

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '23 Sep 2020 08:10'	System	23 Sep 2020 12:18:29

US3402420

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Left Arm (LEFT ARM)'	Abigail Wine (b) (4) (b) (4)	23 Sep 2020 12:18:29

US3402420

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'ONCE'	System	23 Sep 2020 12:18:29

US3402420

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 12:18:29

US3402420

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:52

US3402420

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '23 Sep 2020'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:52

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '07:48'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:50:52

US3402420

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '23 Sep 2020 07:48'	System	23 Sep 2020 12:50:52

US3402420

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:22:36

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '23 Sep 2020'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:51:07

US3402420

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:51:07

US3402420

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:51:07

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '07:51'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:51:07

US3402420

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '23 Sep 2020 07:51'	System	23 Sep 2020 12:51:07

US3402420

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:51:07

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:51:07

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:51:07

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered empty.	System	23 Sep 2020 12:51:07

US3402420

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Sep 2020 12:51:11

US3402420
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '1'	System	23 Sep 2020 12:51:11

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:41:37', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '156943fd-1d43-4af2-9aa4-726eb4c8b250'	System	23 Sep 2020 12:42:03
User entered 'Yes (Y)'	System	23 Sep 2020 12:42:03

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:41:46', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '156943fd-1d43-4af2-9aa4-726eb4c8b250'	System	23 Sep 2020 12:42:03
User entered '97.9'	System	23 Sep 2020 12:42:03

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:41:50', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '156943fd-1d43-4af2-9aa4-726eb4c8b250'	System	23 Sep 2020 12:42:03
User entered 'No (N)'	System	23 Sep 2020 12:42:03

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:41:59', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '156943fd-1d43-4af2-9aa4-726eb4c8b250'	System	23 Sep 2020 12:42:03
User entered '23 Sep 2020 08:41'	System	23 Sep 2020 12:42:03

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Sep 2020 08:30'	System	23 Sep 2020 12:18:29

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Sep 2020 11:00'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:55:23', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fd27a95e-2988-4143-9e90-a9795fb6fc87'	System	24 Sep 2020 01:55:44
User entered 'Yes (Y)'	System	24 Sep 2020 01:55:44

US3402420
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:55:32', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fd27a95e-2988-4143-9e90-a9795fb6fc87'	System	24 Sep 2020 01:55:44
User entered '97.9'	System	24 Sep 2020 01:55:44

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:55:35', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fd27a95e-2988-4143-9e90-a9795fb6fc87'	System	24 Sep 2020 01:55:44
User entered 'No (N)'	System	24 Sep 2020 01:55:44

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:55:40', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fd27a95e-2988-4143-9e90-a9795fb6fc87'	System	24 Sep 2020 01:55:44
User entered '23 Sep 2020 21:55'	System	24 Sep 2020 01:55:44

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Sep 2020 11:55'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 2'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:01:58', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5b1aba0f-382d-4d23-877c-36a2dbaee60c'	System	25 Sep 2020 00:02:19
User entered 'Yes (Y)'	System	25 Sep 2020 00:02:19

FDA-CBER-2022-1614-1771874

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:02:06', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5b1aba0f-382d-4d23-877c-36a2dbaee60c'	System	25 Sep 2020 00:02:19
User entered '97.0'	System	25 Sep 2020 00:02:19

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:02:10', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5b1aba0f-382d-4d23-877c-36a2dbaee60c'	System	25 Sep 2020 00:02:19
User entered 'No (N)'	System	25 Sep 2020 00:02:19

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:02:13', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5b1aba0f-382d-4d23-877c-36a2dbaee60c'	System	25 Sep 2020 00:02:19
User entered '24 Sep 2020 20:02'	System	25 Sep 2020 00:02:19

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:22:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 3'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:19:33', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0a5ad824-90d0-4c41-9588-95b3795b7108'	System	25 Sep 2020 17:19:59
User entered 'Yes (Y)'	System	25 Sep 2020 17:19:59

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:19:47', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0a5ad824-90d0-4c41-9588-95b3795b7108'	System	25 Sep 2020 17:19:59
User entered '97.0'	System	25 Sep 2020 17:19:59

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:19:51', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0a5ad824-90d0-4c41-9588-95b3795b7108'	System	25 Sep 2020 17:19:59
User entered 'No (N)'	System	25 Sep 2020 17:19:59

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:19:56', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0a5ad824-90d0-4c41-9588-95b3795b7108'	System	25 Sep 2020 17:19:59
User entered '25 Sep 2020 13:19'	System	25 Sep 2020 17:19:59

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 4'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:14:35', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '4c573f1e-59a8-4e8f-9464-804b7b2f930c'	System	26 Sep 2020 16:15:29
User entered 'Yes (Y)'	System	26 Sep 2020 16:15:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:19', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '4c573f1e-59a8-4e8f-9464-804b7b2f930c'	System	26 Sep 2020 16:15:29
User entered '96.3'	System	26 Sep 2020 16:15:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:22', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '4c573f1e-59a8-4e8f-9464-804b7b2f930c'	System	26 Sep 2020 16:15:29
User entered 'No (N)'	System	26 Sep 2020 16:15:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:26', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '4c573f1e-59a8-4e8f-9464-804b7b2f930c'	System	26 Sep 2020 16:15:29
User entered '26 Sep 2020 12:15'	System	26 Sep 2020 16:15:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 5'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:33:25', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0455f12a-0d52-4a76-bdac-9e68dd1400c6'	System	27 Sep 2020 16:34:30
User entered 'Yes (Y)'	System	27 Sep 2020 16:34:30

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:34:22', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0455f12a-0d52-4a76-bdac-9e68dd1400c6'	System	27 Sep 2020 16:34:30
User entered '97.7'	System	27 Sep 2020 16:34:30

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:34:26', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0455f12a-0d52-4a76-bdac-9e68dd1400c6'	System	27 Sep 2020 16:34:30
User entered 'No (N)'	System	27 Sep 2020 16:34:30

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:34:29', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0455f12a-0d52-4a76-bdac-9e68dd1400c6'	System	27 Sep 2020 16:34:30
User entered '27 Sep 2020 12:34'	System	27 Sep 2020 16:34:30

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 6'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T16:59:40', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'd9d3bf23-4aeb-4f07-a3c0-6e343153cc67'	System	28 Sep 2020 21:00:00
User entered 'Yes (Y)'	System	28 Sep 2020 21:00:00

US3402420
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T16:59:51', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'd9d3bf23-4aeb-4f07-a3c0-6e343153cc67'	System	28 Sep 2020 21:00:00
User entered '95.9'	System	28 Sep 2020 21:00:00

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T16:59:54', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'd9d3bf23-4aeb-4f07-a3c0-6e343153cc67'	System	28 Sep 2020 21:00:00
User entered 'No (N)'	System	28 Sep 2020 21:00:00

US3402420
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T16:59:58', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'd9d3bf23-4aeb-4f07-a3c0-6e343153cc67'	System	28 Sep 2020 21:00:00
User entered '28 Sep 2020 16:59'	System	28 Sep 2020 21:00:00

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 7'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:22:36
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:54:02', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b000e868-1114-4854-afbe-1266313ba14c'	System	30 Sep 2020 00:55:06
User entered 'Yes (Y)'	System	30 Sep 2020 00:55:06

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:54:48', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b000e868-1114-4854-afbe-1266313ba14c'	System	30 Sep 2020 00:55:06
User entered '96.8'	System	30 Sep 2020 00:55:06

US3402420
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:54:58', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b000e868-1114-4854-afbe-1266313ba14c'	System	30 Sep 2020 00:55:06
User entered 'No (N)'	System	30 Sep 2020 00:55:06

US3402420
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:03', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b000e868-1114-4854-afbe-1266313ba14c'	System	30 Sep 2020 00:55:06
User entered '29 Sep 2020 20:55'	System	30 Sep 2020 00:55:06

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:42:52', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'df3a9a5b-5c93-4974-acf2-352a110d5e49'	System	23 Sep 2020 12:43:10
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 12:43:10

FDA-CBER-2022-1614-1771916

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:42:56', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'df3a9a5b-5c93-4974-acf2-352a110d5e49'	System	23 Sep 2020 12:43:10
User entered 'No (N)'	System	23 Sep 2020 12:43:10

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:42:59', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'df3a9a5b-5c93-4974-acf2-352a110d5e49'	System	23 Sep 2020 12:43:10
User entered 'No (N)'	System	23 Sep 2020 12:43:10

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:43:03', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'df3a9a5b-5c93-4974-acf2-352a110d5e49'	System	23 Sep 2020 12:43:10
User entered 'None (1)'	System	23 Sep 2020 12:43:10

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:43:08', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'df3a9a5b-5c93-4974-acf2-352a110d5e49'	System	23 Sep 2020 12:43:10
User entered '23 Sep 2020 08:43'	System	23 Sep 2020 12:43:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Sep 2020 08:30'	System	23 Sep 2020 12:18:29

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Sep 2020 11:00'	System	23 Sep 2020 12:18:29

FDA-CBER-2022-1614-1771922

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:55:50', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '299be832-59de-4769-872d-ce91ba5f77f2'	System	24 Sep 2020 01:56:11
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 01:56:11

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:55:55', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '299be832-59de-4769-872d-ce91ba5f77f2'	System	24 Sep 2020 01:56:11
User entered 'No (N)'	System	24 Sep 2020 01:56:11

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:55:58', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '299be832-59de-4769-872d-ce91ba5f77f2'	System	24 Sep 2020 01:56:11
User entered 'No (N)'	System	24 Sep 2020 01:56:11

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:56:03', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '299be832-59de-4769-872d-ce91ba5f77f2'	System	24 Sep 2020 01:56:11
User entered 'None (1)'	System	24 Sep 2020 01:56:11

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:56:06', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '299be832-59de-4769-872d-ce91ba5f77f2'	System	24 Sep 2020 01:56:11
User entered '23 Sep 2020 21:56'	System	24 Sep 2020 01:56:11

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Sep 2020 11:55'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 2'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:02:30', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fd42ef88-1259-47ec-84fd-a40c691436ad'	System	25 Sep 2020 00:02:53
User entered 'None (1)'	System	25 Sep 2020 00:02:53

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:02:39', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fd42ef88-1259-47ec-84fd-a40c691436ad'	System	25 Sep 2020 00:02:53
User entered 'No (N)'	System	25 Sep 2020 00:02:53

FDA-CBER-2022-1614-1771933

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:02:44', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fd42ef88-1259-47ec-84fd-a40c691436ad'	System	25 Sep 2020 00:02:53
User entered 'No (N)'	System	25 Sep 2020 00:02:53

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:02:48', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fd42ef88-1259-47ec-84fd-a40c691436ad'	System	25 Sep 2020 00:02:53
User entered 'None (1)'	System	25 Sep 2020 00:02:53

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:02:52', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fd42ef88-1259-47ec-84fd-a40c691436ad'	System	25 Sep 2020 00:02:53
User entered '24 Sep 2020 20:02'	System	25 Sep 2020 00:02:53

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:22:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 3'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:20:17', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '57909318-8b36-48e2-84da-3fe91905a7fc'	System	25 Sep 2020 17:20:33
User entered 'None (1)'	System	25 Sep 2020 17:20:33

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:20:20', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '57909318-8b36-48e2-84da-3fe91905a7fc'	System	25 Sep 2020 17:20:33
User entered 'No (N)'	System	25 Sep 2020 17:20:33

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:22:36
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:20:23', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '57909318-8b36-48e2-84da-3fe91905a7fc'	System	25 Sep 2020 17:20:33
User entered 'No (N)'	System	25 Sep 2020 17:20:33

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:20:27', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '57909318-8b36-48e2-84da-3fe91905a7fc'	System	25 Sep 2020 17:20:33
User entered 'None (1)'	System	25 Sep 2020 17:20:33

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:20:30', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '57909318-8b36-48e2-84da-3fe91905a7fc'	System	25 Sep 2020 17:20:33
User entered '25 Sep 2020 13:20'	System	25 Sep 2020 17:20:33

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 4'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:30', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '6d9c7561-76b3-426b-927e-97ec1309d55b'	System	26 Sep 2020 16:15:48
User entered 'None (1)'	System	26 Sep 2020 16:15:48

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:34', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '6d9c7561-76b3-426b-927e-97ec1309d55b'	System	26 Sep 2020 16:15:48
User entered 'No (N)'	System	26 Sep 2020 16:15:48

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:37', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '6d9c7561-76b3-426b-927e-97ec1309d55b'	System	26 Sep 2020 16:15:48
User entered 'No (N)'	System	26 Sep 2020 16:15:48

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:41', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '6d9c7561-76b3-426b-927e-97ec1309d55b'	System	26 Sep 2020 16:15:48
User entered 'None (1)'	System	26 Sep 2020 16:15:48

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:44', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '6d9c7561-76b3-426b-927e-97ec1309d55b'	System	26 Sep 2020 16:15:48
User entered '26 Sep 2020 12:15'	System	26 Sep 2020 16:15:48

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:22:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 5'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:34:32', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0676a694-5dce-4162-97db-0617898acbd0'	System	27 Sep 2020 16:34:46
User entered 'None (1)'	System	27 Sep 2020 16:34:46

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:34:36', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0676a694-5dce-4162-97db-0617898acbd0'	System	27 Sep 2020 16:34:46
User entered 'No (N)'	System	27 Sep 2020 16:34:46

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:34:40', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0676a694-5dce-4162-97db-0617898acbd0'	System	27 Sep 2020 16:34:46
User entered 'No (N)'	System	27 Sep 2020 16:34:46

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:34:42', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0676a694-5dce-4162-97db-0617898acbd0'	System	27 Sep 2020 16:34:46
User entered 'None (1)'	System	27 Sep 2020 16:34:46

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:34:45', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '0676a694-5dce-4162-97db-0617898acbd0'	System	27 Sep 2020 16:34:46
User entered '27 Sep 2020 12:34'	System	27 Sep 2020 16:34:46

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:22:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 6'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:02', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '06da4bef-3d4e-4946-9edd-18394646ffbd'	System	28 Sep 2020 21:00:21
User entered 'None (1)'	System	28 Sep 2020 21:00:21

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:05', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '06da4bef-3d4e-4946-9edd-18394646ffbd'	System	28 Sep 2020 21:00:21
User entered 'No (N)'	System	28 Sep 2020 21:00:21

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:07', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '06da4bef-3d4e-4946-9edd-18394646ffbd'	System	28 Sep 2020 21:00:21
User entered 'No (N)'	System	28 Sep 2020 21:00:21

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:16', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '06da4bef-3d4e-4946-9edd-18394646ffbd'	System	28 Sep 2020 21:00:21
User entered 'None (1)'	System	28 Sep 2020 21:00:21

FDA-CBER-2022-1614-1771967

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:19', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '06da4bef-3d4e-4946-9edd-18394646ffbd'	System	28 Sep 2020 21:00:21
User entered '28 Sep 2020 17:00'	System	28 Sep 2020 21:00:21

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:22:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 7'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:07', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5ddf4387-d03d-4cc6-9683-6025d9798b3a'	System	30 Sep 2020 00:55:26
User entered 'None (1)'	System	30 Sep 2020 00:55:26

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:11', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5ddf4387-d03d-4cc6-9683-6025d9798b3a'	System	30 Sep 2020 00:55:26
User entered 'No (N)'	System	30 Sep 2020 00:55:26

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:14', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5ddf4387-d03d-4cc6-9683-6025d9798b3a'	System	30 Sep 2020 00:55:26
User entered 'No (N)'	System	30 Sep 2020 00:55:26

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:17', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5ddf4387-d03d-4cc6-9683-6025d9798b3a'	System	30 Sep 2020 00:55:26
User entered 'None (1)'	System	30 Sep 2020 00:55:26

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:22:36
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:22', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '5ddf4387-d03d-4cc6-9683-6025d9798b3a'	System	30 Sep 2020 00:55:26
User entered '29 Sep 2020 20:55'	System	30 Sep 2020 00:55:26

US3402420

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:22:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:43:14', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe00bd22-c0d0-4ac0-9c21-6d8094a68db8'	System	23 Sep 2020 12:43:53
User entered 'None (0)'	System	23 Sep 2020 12:43:53

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:43:16', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe00bd22-c0d0-4ac0-9c21-6d8094a68db8'	System	23 Sep 2020 12:43:53
User entered 'None (0)'	System	23 Sep 2020 12:43:53

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:43:23', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe00bd22-c0d0-4ac0-9c21-6d8094a68db8'	System	23 Sep 2020 12:43:53
User entered 'None (0)'	System	23 Sep 2020 12:43:53

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:43:27', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe00bd22-c0d0-4ac0-9c21-6d8094a68db8'	System	23 Sep 2020 12:43:53
User entered 'None (0)'	System	23 Sep 2020 12:43:53

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:43:29', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe00bd22-c0d0-4ac0-9c21-6d8094a68db8'	System	23 Sep 2020 12:43:53
User entered 'None (0)'	System	23 Sep 2020 12:43:53

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:43:31', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe00bd22-c0d0-4ac0-9c21-6d8094a68db8'	System	23 Sep 2020 12:43:53
User entered 'None (0)'	System	23 Sep 2020 12:43:53

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:43:46', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe00bd22-c0d0-4ac0-9c21-6d8094a68db8'	System	23 Sep 2020 12:43:53
User entered 'No (N)'	System	23 Sep 2020 12:43:53

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:22:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T08:43:49', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe00bd22-c0d0-4ac0-9c21-6d8094a68db8'	System	23 Sep 2020 12:43:53
User entered '23 Sep 2020 08:43'	System	23 Sep 2020 12:43:53

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Sep 2020 08:30'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Sep 2020 11:00'	System	23 Sep 2020 12:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:56:36', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '18df8013-c646-4cd4-88fd-da95ed33bd47'	System	24 Sep 2020 01:57:53
User entered 'None (0)'	System	24 Sep 2020 01:57:53

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:56:38', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '18df8013-c646-4cd4-88fd-da95ed33bd47'	System	24 Sep 2020 01:57:53
User entered 'None (0)'	System	24 Sep 2020 01:57:53

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:56:42', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '18df8013-c646-4cd4-88fd-da95ed33bd47'	System	24 Sep 2020 01:57:53
User entered 'None (0)'	System	24 Sep 2020 01:57:53

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:57:09', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '18df8013-c646-4cd4-88fd-da95ed33bd47'	System	24 Sep 2020 01:57:53
User entered 'None (0)'	System	24 Sep 2020 01:57:53

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:57:31', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '18df8013-c646-4cd4-88fd-da95ed33bd47'	System	24 Sep 2020 01:57:53
User entered 'None (0)'	System	24 Sep 2020 01:57:53

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:22:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:57:33', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '18df8013-c646-4cd4-88fd-da95ed33bd47'	System	24 Sep 2020 01:57:53
User entered 'None (0)'	System	24 Sep 2020 01:57:53

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:57:36', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '18df8013-c646-4cd4-88fd-da95ed33bd47'	System	24 Sep 2020 01:57:53
User entered 'No (N)'	System	24 Sep 2020 01:57:53

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-23T21:57:51', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '18df8013-c646-4cd4-88fd-da95ed33bd47'	System	24 Sep 2020 01:57:53
User entered '23 Sep 2020 21:57'	System	24 Sep 2020 01:57:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '23 Sep 2020 11:55'	System	23 Sep 2020 12:18:29

FDA-CBER-2022-1614-1771999

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 2'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:02:56', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c982ab48-6d44-49f6-a8da-ad3df961e5a4'	System	25 Sep 2020 00:03:15
User entered 'None (0)'	System	25 Sep 2020 00:03:15

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:02:58', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c982ab48-6d44-49f6-a8da-ad3df961e5a4'	System	25 Sep 2020 00:03:15
User entered 'None (0)'	System	25 Sep 2020 00:03:15

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:03:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c982ab48-6d44-49f6-a8da-ad3df961e5a4'	System	25 Sep 2020 00:03:15
User entered 'None (0)'	System	25 Sep 2020 00:03:15

FDA-CBER-2022-1614-1772004

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:03:02', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c982ab48-6d44-49f6-a8da-ad3df961e5a4'	System	25 Sep 2020 00:03:15
User entered 'None (0)'	System	25 Sep 2020 00:03:15

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:03:05', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c982ab48-6d44-49f6-a8da-ad3df961e5a4'	System	25 Sep 2020 00:03:15
User entered 'None (0)'	System	25 Sep 2020 00:03:15

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:03:07', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c982ab48-6d44-49f6-a8da-ad3df961e5a4'	System	25 Sep 2020 00:03:15
User entered 'None (0)'	System	25 Sep 2020 00:03:15

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:03:11', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c982ab48-6d44-49f6-a8da-ad3df961e5a4'	System	25 Sep 2020 00:03:15
User entered 'No (N)'	System	25 Sep 2020 00:03:15

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-24T20:03:13', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c982ab48-6d44-49f6-a8da-ad3df961e5a4'	System	25 Sep 2020 00:03:15
User entered '24 Sep 2020 20:03'	System	25 Sep 2020 00:03:15

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 3'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:20:34', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe68c5e7-aa21-48fc-b6bf-9b5e2f6f8d2e'	System	25 Sep 2020 17:21:12
User entered 'None (0)'	System	25 Sep 2020 17:21:12

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:20:36', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe68c5e7-aa21-48fc-b6bf-9b5e2f6f8d2e'	System	25 Sep 2020 17:21:12
User entered 'None (0)'	System	25 Sep 2020 17:21:12

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:20:40', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe68c5e7-aa21-48fc-b6bf-9b5e2f6f8d2e'	System	25 Sep 2020 17:21:12
User entered 'None (0)'	System	25 Sep 2020 17:21:12

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:20:43', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe68c5e7-aa21-48fc-b6bf-9b5e2f6f8d2e'	System	25 Sep 2020 17:21:12
User entered 'None (0)'	System	25 Sep 2020 17:21:12

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:22:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:20:47', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe68c5e7-aa21-48fc-b6bf-9b5e2f6f8d2e'	System	25 Sep 2020 17:21:12
User entered 'None (0)'	System	25 Sep 2020 17:21:12

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:20:49', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe68c5e7-aa21-48fc-b6bf-9b5e2f6f8d2e'	System	25 Sep 2020 17:21:12
User entered 'None (0)'	System	25 Sep 2020 17:21:12

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:21:06', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe68c5e7-aa21-48fc-b6bf-9b5e2f6f8d2e'	System	25 Sep 2020 17:21:12
User entered 'No (N)'	System	25 Sep 2020 17:21:12

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-25T13:21:09', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fe68c5e7-aa21-48fc-b6bf-9b5e2f6f8d2e'	System	25 Sep 2020 17:21:12
User entered '25 Sep 2020 13:21'	System	25 Sep 2020 17:21:12

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 4'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:22:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:48', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '7fd7059d-c27f-465d-8d36-86f008587c29'	System	26 Sep 2020 16:16:08
User entered 'None (0)'	System	26 Sep 2020 16:16:08

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:50', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '7fd7059d-c27f-465d-8d36-86f008587c29'	System	26 Sep 2020 16:16:08
User entered 'None (0)'	System	26 Sep 2020 16:16:08

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:52', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '7fd7059d-c27f-465d-8d36-86f008587c29'	System	26 Sep 2020 16:16:08
User entered 'None (0)'	System	26 Sep 2020 16:16:08

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:54', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '7fd7059d-c27f-465d-8d36-86f008587c29'	System	26 Sep 2020 16:16:08
User entered 'None (0)'	System	26 Sep 2020 16:16:08

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:56', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '7fd7059d-c27f-465d-8d36-86f008587c29'	System	26 Sep 2020 16:16:08
User entered 'None (0)'	System	26 Sep 2020 16:16:08

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:15:58', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '7fd7059d-c27f-465d-8d36-86f008587c29'	System	26 Sep 2020 16:16:08
User entered 'None (0)'	System	26 Sep 2020 16:16:08

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:16:01', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '7fd7059d-c27f-465d-8d36-86f008587c29'	System	26 Sep 2020 16:16:08
User entered 'No (N)'	System	26 Sep 2020 16:16:08

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-26T12:16:04', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '7fd7059d-c27f-465d-8d36-86f008587c29'	System	26 Sep 2020 16:16:08
User entered '26 Sep 2020 12:16'	System	26 Sep 2020 16:16:08

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 5'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:34:49', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'bb426c85-1c97-4343-abb2-33d08f69bcd2'	System	27 Sep 2020 16:35:12
User entered 'None (0)'	System	27 Sep 2020 16:35:12

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:34:51', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'bb426c85-1c97-4343-abb2-33d08f69bcd2'	System	27 Sep 2020 16:35:12
User entered 'None (0)'	System	27 Sep 2020 16:35:12

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:34:55', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'bb426c85-1c97-4343-abb2-33d08f69bcd2'	System	27 Sep 2020 16:35:12
User entered 'None (0)'	System	27 Sep 2020 16:35:12

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:34:58', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'bb426c85-1c97-4343-abb2-33d08f69bcd2'	System	27 Sep 2020 16:35:12
User entered 'None (0)'	System	27 Sep 2020 16:35:12

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:35:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'bb426c85-1c97-4343-abb2-33d08f69bcd2'	System	27 Sep 2020 16:35:12
User entered 'None (0)'	System	27 Sep 2020 16:35:12

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:35:02', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'bb426c85-1c97-4343-abb2-33d08f69bcd2'	System	27 Sep 2020 16:35:12
User entered 'None (0)'	System	27 Sep 2020 16:35:12

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36
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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:35:08', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'bb426c85-1c97-4343-abb2-33d08f69bcd2'	System	27 Sep 2020 16:35:12
User entered 'No (N)'	System	27 Sep 2020 16:35:12

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-27T12:35:11', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'bb426c85-1c97-4343-abb2-33d08f69bcd2'	System	27 Sep 2020 16:35:12
User entered '27 Sep 2020 12:35'	System	27 Sep 2020 16:35:12

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:22:36
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 6'	System	23 Sep 2020 12:18:29

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:22', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '11d92a44-37d7-455e-9a2d-71191aad3130'	System	28 Sep 2020 21:00:40
User entered 'None (0)'	System	28 Sep 2020 21:00:40

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:24', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '11d92a44-37d7-455e-9a2d-71191aad3130'	System	28 Sep 2020 21:00:40
User entered 'None (0)'	System	28 Sep 2020 21:00:40

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:26', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '11d92a44-37d7-455e-9a2d-71191aad3130'	System	28 Sep 2020 21:00:40
User entered 'None (0)'	System	28 Sep 2020 21:00:40

FDA-CBER-2022-1614-1772048

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:27', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '11d92a44-37d7-455e-9a2d-71191aad3130'	System	28 Sep 2020 21:00:40
User entered 'None (0)'	System	28 Sep 2020 21:00:40

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:29', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '11d92a44-37d7-455e-9a2d-71191aad3130'	System	28 Sep 2020 21:00:40
User entered 'None (0)'	System	28 Sep 2020 21:00:40

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:31', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '11d92a44-37d7-455e-9a2d-71191aad3130'	System	28 Sep 2020 21:00:40
User entered 'None (0)'	System	28 Sep 2020 21:00:40

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36
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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:34', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '11d92a44-37d7-455e-9a2d-71191aad3130'	System	28 Sep 2020 21:00:40
User entered 'No (N)'	System	28 Sep 2020 21:00:40

FDA-CBER-2022-1614-1772052

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-28T17:00:36', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '11d92a44-37d7-455e-9a2d-71191aad3130'	System	28 Sep 2020 21:00:40
User entered '28 Sep 2020 17:00'	System	28 Sep 2020 21:00:40

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

FDA-CBER-2022-1614-1772055

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	23 Sep 2020 12:18:29
User entered 'Day 7'	System	23 Sep 2020 12:18:29

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:25', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '2c35c9dd-40b8-43ff-ba99-92814480bc60'	System	30 Sep 2020 00:55:55
User entered 'None (0)'	System	30 Sep 2020 00:55:55

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:22:36
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:27', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '2c35c9dd-40b8-43ff-ba99-92814480bc60'	System	30 Sep 2020 00:55:55
User entered 'None (0)'	System	30 Sep 2020 00:55:55

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:29', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '2c35c9dd-40b8-43ff-ba99-92814480bc60'	System	30 Sep 2020 00:55:55
User entered 'None (0)'	System	30 Sep 2020 00:55:55

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:32', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '2c35c9dd-40b8-43ff-ba99-92814480bc60'	System	30 Sep 2020 00:55:55
User entered 'None (0)'	System	30 Sep 2020 00:55:55

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:22:36
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:34', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '2c35c9dd-40b8-43ff-ba99-92814480bc60'	System	30 Sep 2020 00:55:55
User entered 'None (0)'	System	30 Sep 2020 00:55:55

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:36', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '2c35c9dd-40b8-43ff-ba99-92814480bc60'	System	30 Sep 2020 00:55:55
User entered 'None (0)'	System	30 Sep 2020 00:55:55

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:48', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '2c35c9dd-40b8-43ff-ba99-92814480bc60'	System	30 Sep 2020 00:55:55
User entered 'No (N)'	System	30 Sep 2020 00:55:55

US3402420
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:22:36
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-09-29T20:55:51', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '2c35c9dd-40b8-43ff-ba99-92814480bc60'	System	30 Sep 2020 00:55:55
User entered '29 Sep 2020 20:55'	System	30 Sep 2020 00:55:55

US3402420

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 12:18:29

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 12:18:29

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 19:48:43

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US3402420

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '30 Sep 2020'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 19:48:43

US3402420
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:22:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 19:48:43

US3402420

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 19:48:43

US3402420

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 19:48:47

US3402420
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '1'	System	05 Oct 2020 19:48:47

US3402420

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:20:24

US3402420

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '7 Oct 2020'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:20:24

US3402420

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:20:24

US3402420

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:20:24

US3402420

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:20:27

US3402420
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '1'	System	27 Oct 2020 14:20:27

US3402420

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:20:49

US3402420

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '14 Oct 2020'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:20:49

US3402420

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:20:49

US3402420

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:20:49

US3402420

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:20:53

US3402420
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '1'	System	27 Oct 2020 14:20:53

US3402420

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:07

US3402420

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '27 Oct 2020'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:07

US3402420

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:07

US3402420
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'VISIT3'	System	27 Oct 2020 14:21:07

US3402420

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:37

US3402420

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '27 Oct 2020'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:37

US3402420

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '08:11'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:37

US3402420
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '27 Oct 2020 08:11'	System	27 Oct 2020 14:21:37

US3402420

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '36.2' C	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:37

US3402420
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:37

US3402420
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:37

US3402420

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '62'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:37

US3402420
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'bpm'	System	27 Oct 2020 14:21:37

US3402420
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '14'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:37

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'breaths/min'	System	27 Oct 2020 14:21:37

US3402420

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '114'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:37

US3402420
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'mmHg'	System	27 Oct 2020 14:21:37

US3402420

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '76'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:37

US3402420
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered 'mmHg'	System	27 Oct 2020 14:21:37

US3402420
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:42

US3402420

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:42

US3402420

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:54

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '27 Oct 2020'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:54

FDA-CBER-2022-1614-1772109

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered '08:15'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '27 Oct 2020 08:15'	System	27 Oct 2020 14:21:54

FDA-CBER-2022-1614-1772111

Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 18:27:51
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:21:58

US3402420

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '1'	System	27 Oct 2020 14:21:58

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 64'	System	22 Aug 2020 13:36:31

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-10-25T09:33:22', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1b24e298-05de-42f5-a274-274a1aa23707'	System	25 Oct 2020 13:33:36
User entered 'No (N)'	System	25 Oct 2020 13:33:36

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-10-25T09:33:27', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1b24e298-05de-42f5-a274-274a1aa23707'	System	25 Oct 2020 13:33:36
User entered 'No (N)'	System	25 Oct 2020 13:33:36

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-10-25T09:33:32', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1b24e298-05de-42f5-a274-274a1aa23707'	System	25 Oct 2020 13:33:36
User entered '25 Oct 2020 09:33:32'	System	25 Oct 2020 13:33:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered '22 Oct 2020 00:01'	System	22 Aug 2020 13:36:31

FDA-CBER-2022-1614-1772118

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered '26 Oct 2020 23:59'	System	22 Aug 2020 13:36:31

FDA-CBER-2022-1614-1772119

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 71'	System	22 Aug 2020 13:36:31

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-10-31T13:50:26', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '99dbd4ef-c390-4251-a42c-3e17e643f2e1'	System	31 Oct 2020 17:50:38
User entered 'No (N)'	System	31 Oct 2020 17:50:38

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-10-31T13:50:31', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '99dbd4ef-c390-4251-a42c-3e17e643f2e1'	System	31 Oct 2020 17:50:38
User entered 'No (N)'	System	31 Oct 2020 17:50:38

FDA-CBER-2022-1614-1772122

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-10-31T13:50:34', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '99dbd4ef-c390-4251-a42c-3e17e643f2e1'	System	31 Oct 2020 17:50:38
User entered '31 Oct 2020 13:50:34'	System	31 Oct 2020 17:50:38

Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered '29 Oct 2020 00:01'	System	22 Aug 2020 13:36:31

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered '02 Nov 2020 23:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 78'	System	22 Aug 2020 13:36:31

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-11-08T10:53:18', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c0f69bbd-262a-4e80-89d3-046b9709da6e'	System	08 Nov 2020 15:53:52
User entered 'Yes (Y)'	System	08 Nov 2020 15:53:52

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-11-08T10:53:31', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c0f69bbd-262a-4e80-89d3-046b9709da6e'	System	08 Nov 2020 15:53:52
User entered 'No (N)'	System	08 Nov 2020 15:53:52

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-11-08T10:53:35', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c0f69bbd-262a-4e80-89d3-046b9709da6e'	System	08 Nov 2020 15:53:52
User entered 'No (N)'	System	08 Nov 2020 15:53:52

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-11-08T10:53:43', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c0f69bbd-262a-4e80-89d3-046b9709da6e'	System	08 Nov 2020 15:53:52
User entered 'No (N)'	System	08 Nov 2020 15:53:52

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-11-08T10:53:48', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'c0f69bbd-262a-4e80-89d3-046b9709da6e'	System	08 Nov 2020 15:53:52
User entered '08 Nov 2020 10:53:48'	System	08 Nov 2020 15:53:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered '05 Nov 2020 00:01'	System	22 Aug 2020 13:36:31

FDA-CBER-2022-1614-1772132

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:52:49
Data entry locked.	System	22 Aug 2020 13:36:31
User entered '09 Nov 2020 23:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40
Data entry locked.	System	22 Aug 2020 13:36:31
User entered 'Day 92'	System	22 Aug 2020 13:36:31

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please 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 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please 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 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please 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 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40

US3402420
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40
Data entry locked.	System	22 Aug 2020 13:36:31
User entered '19 Nov 2020 00:01'	System	22 Aug 2020 13:36:31

US3402420

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:40
Data entry locked.	System	22 Aug 2020 13:36:31
User entered '23 Nov 2020 23:59'	System	22 Aug 2020 13:36:31

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-11-25T08:39:35', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '6617c4e1-4c49-410c-ad2a-2545c1c436c7'	System	25 Nov 2020 13:39:47
User entered 'No (N)'	System	25 Nov 2020 13:39:47

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-11-25T08:39:40', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '6617c4e1-4c49-410c-ad2a-2545c1c436c7'	System	25 Nov 2020 13:39:47
User entered 'No (N)'	System	25 Nov 2020 13:39:47

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-11-25T08:39:43', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '6617c4e1-4c49-410c-ad2a-2545c1c436c7'	System	25 Nov 2020 13:39:47
User entered '25 Nov 2020 08:39:43'	System	25 Nov 2020 13:39:47

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-03T17:59:19', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b3d00885-a3a9-4d9f-b724-e2338d0eb86b'	System	03 Dec 2020 22:59:40
User entered 'No (N)'	System	03 Dec 2020 22:59:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-03T17:59:29', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b3d00885-a3a9-4d9f-b724-e2338d0eb86b'	System	03 Dec 2020 22:59:40
User entered 'No (N)'	System	03 Dec 2020 22:59:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-03T17:59:33', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b3d00885-a3a9-4d9f-b724-e2338d0eb86b'	System	03 Dec 2020 22:59:40
User entered '03 Dec 2020 17:59:33'	System	03 Dec 2020 22:59:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-07T08:54:12', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '69309cfc-c147-41bc-9861-2c27f5bb5866'	System	07 Dec 2020 13:54:25
User entered 'No (N)'	System	07 Dec 2020 13:54:25

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-07T08:54:17', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '69309cfc-c147-41bc-9861-2c27f5bb5866'	System	07 Dec 2020 13:54:25
User entered 'No (N)'	System	07 Dec 2020 13:54:25

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-07T08:54:23', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '69309cfc-c147-41bc-9861-2c27f5bb5866'	System	07 Dec 2020 13:54:25
User entered '07 Dec 2020 08:54:23'	System	07 Dec 2020 13:54:25

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-14T06:14:45', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '377cf51e-a117-4252-8c1c-079f5ae70617'	System	14 Dec 2020 11:14:58
User entered 'No (N)'	System	14 Dec 2020 11:14:58

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-14T06:14:51', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '377cf51e-a117-4252-8c1c-079f5ae70617'	System	14 Dec 2020 11:14:58
User entered 'No (N)'	System	14 Dec 2020 11:14:58

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-14T06:14:56', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '377cf51e-a117-4252-8c1c-079f5ae70617'	System	14 Dec 2020 11:14:58
User entered '14 Dec 2020 06:14:56'	System	14 Dec 2020 11:14:58

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-21T16:57:56', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1df4cf54-1d49-49b4-8c66-bb5e5263be3e'	System	21 Dec 2020 21:58:09
User entered 'No (N)'	System	21 Dec 2020 21:58:09

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-21T16:58:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1df4cf54-1d49-49b4-8c66-bb5e5263be3e'	System	21 Dec 2020 21:58:09
User entered 'No (N)'	System	21 Dec 2020 21:58:09

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-21T16:58:05', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '1df4cf54-1d49-49b4-8c66-bb5e5263be3e'	System	21 Dec 2020 21:58:09
User entered '21 Dec 2020 16:58:05'	System	21 Dec 2020 21:58:09

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-29T19:32:54', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '7d69fb35-8996-4a53-a199-fcf8fa73dd31'	System	30 Dec 2020 00:33:06
User entered 'No (N)'	System	30 Dec 2020 00:33:06

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-29T19:32:58', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '7d69fb35-8996-4a53-a199-fcf8fa73dd31'	System	30 Dec 2020 00:33:06
User entered 'No (N)'	System	30 Dec 2020 00:33:06

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2020-12-29T19:33:03', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '7d69fb35-8996-4a53-a199-fcf8fa73dd31'	System	30 Dec 2020 00:33:06
User entered '29 Dec 2020 19:33:03'	System	30 Dec 2020 00:33:06

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-01-04T10:38:54', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '2e268ac9-05ca-42a1-9f4e-f85ad0424001'	System	04 Jan 2021 15:39:07
User entered 'No (N)'	System	04 Jan 2021 15:39:07

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-01-04T10:38:58', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '2e268ac9-05ca-42a1-9f4e-f85ad0424001'	System	04 Jan 2021 15:39:07
User entered 'No (N)'	System	04 Jan 2021 15:39:07

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-01-04T10:39:01', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '2e268ac9-05ca-42a1-9f4e-f85ad0424001'	System	04 Jan 2021 15:39:07
User entered '04 Jan 2021 10:39:01'	System	04 Jan 2021 15:39:07

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-01-11T09:03:36', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8ba6e20a-4089-4cca-a4af-89e1307840f4'	System	11 Jan 2021 14:03:45
User entered 'No (N)'	System	11 Jan 2021 14:03:45

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-01-11T09:03:27', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8ba6e20a-4089-4cca-a4af-89e1307840f4'	System	11 Jan 2021 14:03:45
User entered 'No (N)'	System	11 Jan 2021 14:03:45

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-01-11T09:03:42', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8ba6e20a-4089-4cca-a4af-89e1307840f4'	System	11 Jan 2021 14:03:45
User entered '11 Jan 2021 09:03:42'	System	11 Jan 2021 14:03:45

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-01-18T08:16:40', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fcd63f60-0b0a-4a04-b992-16b787080084'	System	18 Jan 2021 13:16:48
User entered 'No (N)'	System	18 Jan 2021 13:16:48

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-01-18T08:16:42', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fcd63f60-0b0a-4a04-b992-16b787080084'	System	18 Jan 2021 13:16:48
User entered 'No (N)'	System	18 Jan 2021 13:16:48

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-01-18T08:16:45', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'fcd63f60-0b0a-4a04-b992-16b787080084'	System	18 Jan 2021 13:16:48
User entered '18 Jan 2021 08:16:45'	System	18 Jan 2021 13:16:48

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-01-25T08:37:09', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '3f47fe65-b09f-4bad-92b6-a3c784f408e2'	System	25 Jan 2021 13:37:21
User entered 'No (N)'	System	25 Jan 2021 13:37:21

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-01-25T08:37:12', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '3f47fe65-b09f-4bad-92b6-a3c784f408e2'	System	25 Jan 2021 13:37:21
User entered 'No (N)'	System	25 Jan 2021 13:37:21

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-01-25T08:37:15', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '3f47fe65-b09f-4bad-92b6-a3c784f408e2'	System	25 Jan 2021 13:37:21
User entered '25 Jan 2021 08:37:15'	System	25 Jan 2021 13:37:21

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-01T09:47:04', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '64a2997c-9b84-468a-9463-01777e7ef727'	System	01 Feb 2021 14:47:13
User entered 'No (N)'	System	01 Feb 2021 14:47:13

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-01T09:47:06', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '64a2997c-9b84-468a-9463-01777e7ef727'	System	01 Feb 2021 14:47:13
User entered 'No (N)'	System	01 Feb 2021 14:47:13

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-01T09:47:10', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '64a2997c-9b84-468a-9463-01777e7ef727'	System	01 Feb 2021 14:47:13
User entered '01 Feb 2021 09:47:10'	System	01 Feb 2021 14:47:13

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-08T20:42:55', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'bc69d0a6-909f-46e1-876a-a4ac1337b77b'	System	09 Feb 2021 01:43:08
User entered 'No (N)'	System	09 Feb 2021 01:43:08

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-08T20:43:02', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'bc69d0a6-909f-46e1-876a-a4ac1337b77b'	System	09 Feb 2021 01:43:08
User entered 'No (N)'	System	09 Feb 2021 01:43:08

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-08T20:43:06', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'bc69d0a6-909f-46e1-876a-a4ac1337b77b'	System	09 Feb 2021 01:43:08
User entered '08 Feb 2021 20:43:06'	System	09 Feb 2021 01:43:08

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-18T12:23:58', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'f07eb116-5b2b-4116-b233-4718f8cd7568'	System	18 Feb 2021 17:24:30
User entered 'No (N)'	System	18 Feb 2021 17:24:30

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-18T12:24:04', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'f07eb116-5b2b-4116-b233-4718f8cd7568'	System	18 Feb 2021 17:24:30
User entered 'No (N)'	System	18 Feb 2021 17:24:30

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-18T12:24:09', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'f07eb116-5b2b-4116-b233-4718f8cd7568'	System	18 Feb 2021 17:24:30
User entered '18 Feb 2021 12:24:09'	System	18 Feb 2021 17:24:30

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-22T09:26:04', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'a8816afe-6015-46e2-9c59-29adaf41379b'	System	22 Feb 2021 14:26:18
User entered 'No (N)'	System	22 Feb 2021 14:26:18

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-22T09:26:09', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'a8816afe-6015-46e2-9c59-29adaf41379b'	System	22 Feb 2021 14:26:18
User entered 'No (N)'	System	22 Feb 2021 14:26:18

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-22T09:26:12', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'a8816afe-6015-46e2-9c59-29adaf41379b'	System	22 Feb 2021 14:26:18
User entered '22 Feb 2021 09:26:12'	System	22 Feb 2021 14:26:18

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 01:11:40

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-01T08:04:58-05:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '03cd47b3-7cc5-4b9d-bb66-9b89cd514ceb'	System	01 Mar 2021 13:05:28
User entered 'No (N)'	System	01 Mar 2021 13:05:28

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-01T08:05:02-05:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '03cd47b3-7cc5-4b9d-bb66-9b89cd514ceb'	System	01 Mar 2021 13:05:28
User entered 'No (N)'	System	01 Mar 2021 13:05:28

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-01T08:05:07-05:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '03cd47b3-7cc5-4b9d-bb66-9b89cd514ceb'	System	01 Mar 2021 13:05:28
User entered '01 Mar 2021 08:05:07'	System	01 Mar 2021 13:05:28

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 01:11:40

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-10T12:01:11-05:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '3419b562-20b3-431f-975f-c157d8d58baa'	System	10 Mar 2021 17:04:11
User entered 'No (N)'	System	10 Mar 2021 17:04:11

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-10T12:01:17-05:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '3419b562-20b3-431f-975f-c157d8d58baa'	System	10 Mar 2021 17:04:11
User entered 'No (N)'	System	10 Mar 2021 17:04:11

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-10T12:01:20-05:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '3419b562-20b3-431f-975f-c157d8d58baa'	System	10 Mar 2021 17:04:11
User entered '10 Mar 2021 12:01:20'	System	10 Mar 2021 17:04:11

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-17T20:55:34-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8b89e37d-eece-4064-952c-2b89ffa745e3'	System	18 Mar 2021 00:55:48
User entered 'No (N)'	System	18 Mar 2021 00:55:48

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-17T20:55:40-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8b89e37d-eece-4064-952c-2b89ffa745e3'	System	18 Mar 2021 00:55:48
User entered 'No (N)'	System	18 Mar 2021 00:55:48

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-17T20:55:43-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '8b89e37d-eece-4064-952c-2b89ffa745e3'	System	18 Mar 2021 00:55:48
User entered '17 Mar 2021 20:55:43'	System	18 Mar 2021 00:55:48

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 01:11:40

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 01:11:40

FDA-CBER-2022-1614-1772263

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-23T11:56:21-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b8b5916c-5f3d-4a8a-8ac8-83c94b613083'	System	23 Mar 2021 15:56:35
User entered 'No (N)'	System	23 Mar 2021 15:56:35

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-23T11:56:25-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b8b5916c-5f3d-4a8a-8ac8-83c94b613083'	System	23 Mar 2021 15:56:35
User entered 'No (N)'	System	23 Mar 2021 15:56:35

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-23T11:56:27-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'b8b5916c-5f3d-4a8a-8ac8-83c94b613083'	System	23 Mar 2021 15:56:35
User entered '23 Mar 2021 11:56:27'	System	23 Mar 2021 15:56:35

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-31T18:24:54-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '266ad76b-588c-4b1b-ab72-aa7bff1be0e1'	System	31 Mar 2021 22:25:02
User entered 'No (N)'	System	31 Mar 2021 22:25:02

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-31T18:24:57-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '266ad76b-588c-4b1b-ab72-aa7bff1be0e1'	System	31 Mar 2021 22:25:02
User entered 'No (N)'	System	31 Mar 2021 22:25:02

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-03-31T18:25:00-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '266ad76b-588c-4b1b-ab72-aa7bff1be0e1'	System	31 Mar 2021 22:25:02
User entered '31 Mar 2021 18:25:00'	System	31 Mar 2021 22:25:02

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-04-05T13:15:12-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '4a1c5fd5-7f64-435f-92d8-1e6bd3646d4a'	System	05 Apr 2021 17:15:22
User entered 'No (N)'	System	05 Apr 2021 17:15:22

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-04-05T13:15:15-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '4a1c5fd5-7f64-435f-92d8-1e6bd3646d4a'	System	05 Apr 2021 17:15:22
User entered 'No (N)'	System	05 Apr 2021 17:15:22

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-04-05T13:15:17-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '4a1c5fd5-7f64-435f-92d8-1e6bd3646d4a'	System	05 Apr 2021 17:15:22
User entered '05 Apr 2021 13:15:17'	System	05 Apr 2021 17:15:22

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-04-12T08:26:25-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '91313467-c2d0-4068-a4f2-f580f35045db'	System	12 Apr 2021 12:26:39
User entered 'No (N)'	System	12 Apr 2021 12:26:39

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-04-12T08:26:28-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '91313467-c2d0-4068-a4f2-f580f35045db'	System	12 Apr 2021 12:26:39
User entered 'No (N)'	System	12 Apr 2021 12:26:39

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-04-12T08:26:32-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '91313467-c2d0-4068-a4f2-f580f35045db'	System	12 Apr 2021 12:26:39
User entered '12 Apr 2021 08:26:32'	System	12 Apr 2021 12:26:39

FDA-CBER-2022-1614-1772285

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-04-19T13:19:58-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'ea8e47be-69f4-403c-8a81-0a51b8c4c878'	System	19 Apr 2021 17:20:15
User entered 'No (N)'	System	19 Apr 2021 17:20:15

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-04-19T13:20:02-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'ea8e47be-69f4-403c-8a81-0a51b8c4c878'	System	19 Apr 2021 17:20:15
User entered 'No (N)'	System	19 Apr 2021 17:20:15

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-04-19T13:20:05-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'ea8e47be-69f4-403c-8a81-0a51b8c4c878'	System	19 Apr 2021 17:20:15
User entered '19 Apr 2021 13:20:05'	System	19 Apr 2021 17:20:15

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-04-26T08:07:12-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'ae36c5ad-227c-408c-a147-d90ead7c1bcf'	System	26 Apr 2021 12:07:28
User entered 'No (N)'	System	26 Apr 2021 12:07:28

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-04-26T08:07:21-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'ae36c5ad-227c-408c-a147-d90ead7c1bcf'	System	26 Apr 2021 12:07:28
User entered 'No (N)'	System	26 Apr 2021 12:07:28

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-04-26T08:07:25-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'ae36c5ad-227c-408c-a147-d90ead7c1bcf'	System	26 Apr 2021 12:07:28
User entered '26 Apr 2021 08:07:25'	System	26 Apr 2021 12:07:28

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-05-03T10:52:10-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '16c32ea2-5dd0-4ca8-9cf1-996c777778ad'	System	03 May 2021 14:52:19
User entered 'No (N)'	System	03 May 2021 14:52:19

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-05-03T10:52:12-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '16c32ea2-5dd0-4ca8-9cf1-996c777778ad'	System	03 May 2021 14:52:19
User entered 'No (N)'	System	03 May 2021 14:52:19

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-05-03T10:52:15-04:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: '16c32ea2-5dd0-4ca8-9cf1-996c777778ad'	System	03 May 2021 14:52:19
User entered '03 May 2021 10:52:15'	System	03 May 2021 14:52:19

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 01:11:40

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 01:11:40

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:11:40

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:11:40

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:11:40

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 01:11:40

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:11:40

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 01:11:40

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US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 01:11:40

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:11:40

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:11:40

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 01:11:40

FDA-CBER-2022-1614-1772505

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:11:40

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 01:11:40

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 01:11:40

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 01:11:40

FDA-CBER-2022-1614-1772524

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:22:36
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 01:11:40

US3402420

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:40
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 01:11:40

US3402420

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:22:36

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 07:07:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-28T13:33:04-05:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'deb9d8db-862e-4ce5-bddb-71dc216cba6f'	System	28 Feb 2021 18:33:14
User entered 'No (N)'	System	28 Feb 2021 18:33:14

US3402420

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:22:36

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:07:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1393E6D1-AD5C-470C-B064-5D1D5722554B)', Time: '2021-02-28T13:33:11-05:00', User OID: 'PatientReportedOutcome (US3402420)', ODM File OID: 'deb9d8db-862e-4ce5-bddb-71dc216cba6f'	System	28 Feb 2021 18:33:14
User entered '28 Feb 2021 18:33:11'	System	28 Feb 2021 18:33:14

US3402420

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:32:20
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 15:02:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:32:20
User entered '16 Nov 2020'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 15:02:32

FDA-CBER-2022-1614-1772540

US3402420

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:32:20
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 15:02:32

US3402420

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:32:20
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Nov 2020 15:02:32

US3402420

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:32:20
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Nov 2020 15:02:23

US3402420
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:04:59
User entered '1'	System	16 Nov 2020 15:02:23

US3402420

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Dec 2020 13:13:03

US3402420

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Dec 2020'	Traci Hull (b) (4) (b) (4)	24 Dec 2020 13:13:03

US3402420
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:22:36
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	24 Dec 2020 13:13:03

US3402420
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:22:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Dec 2020 13:13:03

US3402420

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Dec 2020 13:12:50

US3402420

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User entered '1'	System	24 Dec 2020 13:12:50

US3402420
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 16:03:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '18 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 16:03:13

US3402420

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 16:03:13

US3402420

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 16:03:13

US3402420

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	18 Jan 2021 16:03:43

US3402420

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User entered '1'	System	18 Jan 2021 16:03:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 14:07:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '17 Feb 2021'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 14:07:29

US3402420

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 14:07:29

Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:22:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Feb 2021 14:07:29

US3402420

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Feb 2021 14:07:34

US3402420
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:11
User entered '1'	System	18 Feb 2021 14:07:34

US3402420

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:22:57

US3402420

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '17 Mar 2021'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:22:57

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 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:22:57

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US3402420
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User entered 'VISIT4'	System	17 Mar 2021 14:22:57

US3402420

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:33:13

US3402420

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:33:13

US3402420

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:33:13

US3402420

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User entered empty.	System	31 Mar 2021 16:33:13

US3402420
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:33:13

US3402420
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:33:13

US3402420
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:33:13

US3402420
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:33:13

US3402420
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User entered empty.	System	31 Mar 2021 16:33:13

US3402420
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:33:13

US3402420
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User entered empty.	System	31 Mar 2021 16:33:13

US3402420

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:33:13

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User entered empty.	System	31 Mar 2021 16:33:13

US3402420

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 16:33:13

US3402420
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User entered empty.	System	31 Mar 2021 16:33:13

Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49

US3402420
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49

US3402420

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:24:18

US3402420

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:24:18

Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:22:36
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
Comment added 'OL-3 KIT WAS USED PER PROTOCOL DUE TO BOTH VISITS BEING DONE AT SAME TIME.'.	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:26:22
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:24:29

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '17 Mar 2021'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:24:29

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Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:22:36
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '10:07'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:24:29

US3402420

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User entered '17 Mar 2021 10:07'	System	17 Mar 2021 14:24:29

US3402420

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:24:32

US3402420
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:00:49
User entered '1'	System	17 Mar 2021 14:24:32

US3402420

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 18:45:51

US3402420

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '19 Apr 2021'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 18:45:51

US3402420

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 18:45:51

US3402420
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:22:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 18:45:51

US3402420

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	19 Apr 2021 18:45:55

US3402420
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 18:45:55

US3402420

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

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:50:20

US3402420

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

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:50:20

US3402420

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

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:50:20

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 14:50:20

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '06 Jan 2021'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:50:51

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '0'	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 14:14:39
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:37:41

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:50:51

US3402420

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 06:11:03
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 14:14:42
User entered 'Amendment 6 or later (Amendment 6 or later)'	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 14:14:39
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:10:06
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:37:41

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:50:51

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Placebo (Placebo)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:50:51

US3402420

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 08:08:34
User entered 'Placebo (Placebo)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:50:51

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 08:08:34
User entered 'Placebo (Placebo)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:50:51

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:50:51

US3402420
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:22:36

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered '1'	System	19 Jan 2021 14:50:51

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered '1'	System	19 Jan 2021 14:50:51

US3402420
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:22:36
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered empty.	System	19 Jan 2021 14:53:50
DataPoint set to visible.	System	19 Jan 2021 14:50:51

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered empty.	System	19 Jan 2021 14:53:50
DataPoint set to visible.	System	19 Jan 2021 14:50:51

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '08:42'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered '19 Jan 2021 08:42'	System	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '97.5' F	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '58'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered 'bpm'	System	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '14'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered 'breaths/min'	System	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '110'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered 'mmHg'	System	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '77'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered 'mmHg'	System	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered empty.	System	19 Jan 2021 14:53:50
DataPoint set to visible.	System	19 Jan 2021 14:50:51

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '09:28'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered '19 Jan 2021 09:28'	System	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
User entered '98.1' F	Traci Hull (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '84'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:22:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered 'bpm'	System	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '14'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered 'breaths/min'	System	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '113'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered 'mmHg'	System	19 Jan 2021 14:53:50

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '76'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:53:50

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered 'mmHg'	System	19 Jan 2021 14:53:50

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:54:07

US3402420

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:54:07

US3402420

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:54:23

US3402420

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:54:23

US3402420

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:54:23

Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:22:36

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered 'mRNA-1273'	System	19 Jan 2021 14:54:23
DataPoint set to visible.	System	19 Jan 2021 14:50:51

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:54:23

US3402420

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '08:55'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:54:23

US3402420

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered '19 Jan 2021 08:55'	System	19 Jan 2021 14:54:23

US3402420

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:54:23

US3402420

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered 'ONCE'	System	19 Jan 2021 14:54:23

US3402420

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 14:54:23

US3402420

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:51:04

US3402420

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:51:04

US3402420

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '08:28'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:51:04

US3402420

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered '19 Jan 2021 08:28'	System	19 Jan 2021 14:51:04

US3402420

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:51:14

US3402420

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:22:36

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:51:14

US3402420

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:22:36

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '08:23'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:51:14

US3402420

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:22:36

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered '19 Jan 2021 08:23'	System	19 Jan 2021 14:51:14

US3402420

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

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 14:51:24

US3402420

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

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:44
User entered '1'	System	19 Jan 2021 14:51:24

US3402420
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:18:46

US3402420

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '26 Jan 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:18:46

US3402420

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:18:55
User entered 'Contact Not Made (CONTACT NOT MADE)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:18:46

US3402420
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:22:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	16 Feb 2021 16:18:55
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	16 Feb 2021 16:18:46
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:18:46

US3402420

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:19:12

US3402420

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:19
User entered '1'	System	16 Feb 2021 16:19:12

US3402420

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:19
User entered '1'	System	16 Feb 2021 16:19:12
DataPoint set to visible.	System	16 Feb 2021 16:19:12

US3402420
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:19:31

US3402420
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '16 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:19:31

US3402420
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36

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 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:19:31

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered 'OLD29'	System	16 Feb 2021 16:19:31

US3402420
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:22:36
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '16 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '08:15'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered '16 Feb 2021 08:15'	System	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '36.6' C	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '66'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

US3402420
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:22:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered 'bpm'	System	16 Feb 2021 16:20:57

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '16'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered 'breaths/min'	System	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '106'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered 'mmHg'	System	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '65'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

US3402420
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:22:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered 'mmHg'	System	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '16 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

US3402420
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '09:33'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered '16 Feb 2021 09:33'	System	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '36.6' C	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

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US3402420
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:22:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '51'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

US3402420
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:22:36
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered 'bpm'	System	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '16'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered 'breaths/min'	System	16 Feb 2021 16:20:57

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US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '97'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered 'mmHg'	System	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '68'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:20:57

US3402420
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:22:36
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered 'mmHg'	System	16 Feb 2021 16:20:57

US3402420

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4)	16 Feb 2021 16:21:17

US3402420

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '16 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:21:17

US3402420

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:21:37

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:21:37

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:21:37

US3402420

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered 'mRNA-1273'	System	16 Feb 2021 16:21:37
DataPoint set to visible.	System	16 Feb 2021 16:19:12

US3402420

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '16 Feb 2021'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:21:37

US3402420

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '08:56'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:21:37

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered '16 Feb 2021 08:56'	System	16 Feb 2021 16:21:37

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:21:37

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What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered 'ONCE'	System	16 Feb 2021 16:21:37

FDA-CBER-2022-1614-1772729

US3402420
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:22:36
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered 'INTRAMUSCULAR'	System	16 Feb 2021 16:21:37

US3402420
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Feb 2021 16:21:43

US3402420
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:22:36
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:51:40
User entered '1'	System	16 Feb 2021 16:21:43

US3402420
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:57:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Feb 2021 15:27:57

US3402420

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:57:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Feb 2021'	Traci Hull (b) (4) (b) (4)	23 Feb 2021 15:27:57

US3402420

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:57:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	23 Feb 2021 15:27:57

FDA-CBER-2022-1614-1772735

US3402420
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:22:36
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:57:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	23 Feb 2021 15:27:57

US3402420

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:57:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Feb 2021 15:28:02

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:57:40
User entered '1'	System	23 Feb 2021 15:28:02

US3402420
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:26:44

US3402420

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '17 Mar 2021'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:26:44

US3402420
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36

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 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:26:44

FDA-CBER-2022-1614-1772741

US3402420
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:22:36
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User entered 'OLD57'	System	17 Mar 2021 14:26:44

US3402420

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:02

US3402420
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:02

US3402420

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:02

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User entered empty.	System	17 Mar 2021 14:27:02

US3402420
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:02

US3402420
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:02

US3402420
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:02

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:02

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User entered empty.	System	17 Mar 2021 14:27:02

FDA-CBER-2022-1614-1772751

US3402420
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:02

US3402420
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User entered empty.	System	17 Mar 2021 14:27:02

US3402420
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:02

US3402420
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User entered empty.	System	17 Mar 2021 14:27:02

US3402420
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User entered empty.	System	17 Mar 2021 14:27:02

US3402420
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53

US3402420
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:22:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:06

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:06

US3402420

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:16

US3402420

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '17 Mar 2021'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '10:07'	Traci Hull (b) (4) (b) (4)	17 Mar 2021 14:27:16

US3402420

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:53
User entered '17 Mar 2021 10:07'	System	17 Mar 2021 14:27:16

US3402420

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:22:36

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
Signature has been broken.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 13:39:13
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 13:39:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:51:56
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:39:37

US3402420

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

AEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'USA-US059-2021-mRNA-1273-P301000014'	System	20 Apr 2021 17:22:42
User entered 'New'	(b) (4), (b) (6)	20 Apr 2021 17:22:42

US3402420

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina unstable, LLT: Unstable angina - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:21:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:21:40
Data point term sent to Coder	System	19 Apr 2021 14:20:34
User entered 'Unstable Angina'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

US3402420

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

US3402420

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '19 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

US3402420

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '24 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

US3402420

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Severity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

US3402420
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:22:36

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '24 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

US3402420
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:22:36
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4) (b) (4)	19 Apr 2021 14:19:40

US3402420

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

US3402420

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

US3402420

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

None

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

US3402420

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Could you please clarify "history of defibrillator"; does subject have an implantable cardioverter defibrillator, or was he treated with defibrillation with MI? ' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 15:09:09
User opened query 'PV Query: Did subject receive any treatment medications in the hospital besides continuation of his previous medications? 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)	27 Apr 2021 15:09:00
User opened query 'PV Query: Please provide dates for laboratory/diagnostic tests mentioned in narrative. If any additional results are available, 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)	27 Apr 2021 15:08:51
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Narrative

Audit	User	Time (GMT)
User entered 'PATIENT PRESENTED TO EMERGENCY ROOM WITH LEFT SIDED CHEST PAIN THAT HE HAD BEEN HAVING FOR 3-4 DAYS. PATIENT DENIED ANY CHANGES IN ACTIVITY. PATIENT DOES HAVE A HISTORY OF DEFIBRILLATOR AND MYOCARDIAL INFARCTION WITH 4 STENTS PLACED IN DECEMBER OF 2019. SUBJECT DID HAVE A CMP, PROTIME, APTT, AND TROPONIN ALL OF WHICH RETURNED NORMAL RESULTS.SUBJECTS LOOD PRESSURE RANGED FROM 112/82-120/84SUBJECT DID HAVE COVID TEST THAT WAS NEGATIVE. CHEST XRAY THAT WAS NEGATIVE, HE ALSO HAD A ECG THAT SHOWED BRADICARDIA HEART REATE OF 54, A PREVIOUS INFARCT IN THE ANTEROLATERAL/INFERIOR LEADS, BUTno acute ST wave changes.Subject also had echo cardiagram whch showed a decrease inEF of 19% from previous echo, and a stress test which showed no changes. Subject will continue aspirin 81 mg, coreg 6.25 mg twice daily, Brillinta 90mg twice daily, and atorvastatin 40mg daily.' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:27:25
User entered 'Patient presented to emergency room with left sided chest pain that he had been having for 3-4 days. Patient denied any changes in activity. Patient does have a history of defibrillator and Myocardial infarction with 4 stents placed in December of 2019. Subject did have a CMP, Protime, APTT, and Troponin all of which returned normal results.Subjects lood pressure ranged from 112/82-120/84Subject did have covid test that was negative. Chest Xray that was negative, He also had a ECG that showed Bradicardia heart reate of 54, a previous infarct in the anterolateral/inferior leads, but'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 14:19:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 14:19:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:49:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 21:34:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 21:34:47
Data point term sent to Coder	System	22 Aug 2020 14:51:24
User entered 'AMIODARONE'	(b) (4), (b) (6)	22 Aug 2020 14:51:14

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:51:14

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:22:36
Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User closed query 'Per DM CLR: Please update the indication to reflect the type of CARDIAC DYSRHYTHMIA (e.g. Atrial fibrillation, Supraventricular tachycardia). Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 17:55:39
Query 'Per DM CLR: Please update the indication to reflect the type of CARDIAC DYSRHYTHMIA (e.g. Atrial fibrillation, Supraventricular tachycardia). Please reconcile with Med History eCRF as appropriate. ' answered with 'HEART ATTACK' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	21 Sep 2020 19:32:05
User opened query 'Per DM CLR: Please update the indication to reflect the type of CARDIAC DYSRHYTHMIA (e.g. Atrial fibrillation, Supraventricular tachycardia). Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:07:19
User entered 'CARDIAC DYSRHYTHMIA'	(b) (4), (b) (6)	22 Aug 2020 14:51:14

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '200'	(b) (4), (b) (6)	22 Aug 2020 14:51:14

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 14:51:14

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:51:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Aug 2020 14:51:14

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:51:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 14:51:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:51:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered '03 Jan 2020'	(b) (4), (b) (6)	22 Aug 2020 14:51:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:51:14

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:22:36

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:51:14

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:51:14

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:51:14

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 14:51:14

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 14:51:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 14:51:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Aug 2020 10:19:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 10:19:40
Data point term sent to Coder	System	22 Aug 2020 14:52:24
User entered 'ASPIRIN'	(b) (4), (b) (6)	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User closed query 'Per DM CLR: Please update the indication to reflect the type of CARDIAC DYSRHYTHMIA (e.g. Atrial fibrillation, Supraventricular tachycardia). Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 17:56:08
Query 'Per DM CLR: Please update the indication to reflect the type of CARDIAC DYSRHYTHMIA (e.g. Atrial fibrillation, Supraventricular tachycardia). Please reconcile with Med History eCRF as appropriate. ' answered with 'HEART ATTACK' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	21 Sep 2020 19:31:34
User opened query 'Per DM CLR: Please update the indication to reflect the type of CARDIAC DYSRHYTHMIA (e.g. Atrial fibrillation, Supraventricular tachycardia). Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:07:30
User entered 'CARDIAC DYSRHYTHMIA'	(b) (4), (b) (6)	22 Aug 2020 14:52:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered '81'	(b) (4), (b) (6)	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '03 Jan 2020'	(b) (4), (b) (6)	22 Aug 2020 14:52:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:52:11

FDA-CBER-2022-1614-1772834

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 14:52:11

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:55:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:55:10
Data point term sent to Coder	System	22 Aug 2020 14:54:25
User entered 'ATORVASTATIN'	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '40'	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '03 Jan 2020'	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 14:54:16

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:57:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:57:11
Data point term sent to Coder	System	22 Aug 2020 14:56:26
User entered 'CARVEDILOL'	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered 'CORONARY ARTERY DISEASE'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '6.25'	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '03 Jan 2020'	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 14:55:53

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 05:43:34
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 05:43:34
	(b) (4)	
Data point term sent to Coder	System	22 Aug 2020 14:58:27
User entered 'PANTOPRAZOLE'	(b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'GASTROESAPHAGEAL REFLUX DISEASE'	(b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered '40'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered 'UN UNK 2018'	(b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 14:57:36

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: SACUBITRIL VALSARTAN SODIUM HYDRATE, PRODUCTSYNONYM: ENTRESTO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Oct 2020 21:02:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 21:02:25
Data point term sent to Coder	System	26 Oct 2020 15:47:58
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 15:47:53
User entered 'ENTRESTO (sacubitril/valsartan)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 15:47:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: SACUBITRIL VALSARTAN SODIUM HYDRATE, PRODUCTSYNONYM: ENTRESTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 15:00:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 15:00:12
Data point term sent to Coder	System	22 Aug 2020 14:59:28
User entered 'ENTRESTO'	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'CONGESTIVE HEART FAILURE'	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User closed query 'Per CDM: Thank you for updating the dose per administration. However, please consider updating the corresponding dose unit as well.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:00:22
Query 'Per CDM: Thank you for updating the dose per administration. However, please consider updating the corresponding dose unit as well.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	27 Oct 2020 19:30:47
User entered '97/103' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	27 Oct 2020 19:30:34
User opened query 'Per CDM: Thank you for updating the dose per administration. However, please consider updating the corresponding dose unit as well.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:44:03
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 49/51).' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:44:03
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 49/51).' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 15:48:02
User entered '97mg/103mg' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 15:47:10
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 49/51).' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:38:14
User entered '1'	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'mg (mg)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	27 Oct 2020 19:30:34
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered '10 Mar 2020'	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 14:58:40

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 07:22:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 07:22:43
Data point term sent to Coder	System	22 Aug 2020 15:00:28
User entered 'TICAGRELOR'	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User closed query 'Per DM CLR: Please update the indication to reflect the type of CARDIAC DYSRHYTHMIA (e.g. Atrial fibrillation, Supraventricular tachycardia). Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 17:56:20
Query 'Per DM CLR: Please update the indication to reflect the type of CARDIAC DYSRHYTHMIA (e.g. Atrial fibrillation, Supraventricular tachycardia). Please reconcile with Med History eCRF as appropriate. ' answered with 'HEART ATTACK' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	21 Sep 2020 19:32:21
User opened query 'Per DM CLR: Please update the indication to reflect the type of CARDIAC DYSRHYTHMIA (e.g. Atrial fibrillation, Supraventricular tachycardia). Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:07:45
User entered 'CARDIAC DYSRHYTHMIA'	(b) (4), (b) (6)	22 Aug 2020 15:00:27

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '90'	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '03 Jan 2020'	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 15:00:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 15:00:27

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 15:02:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 15:02:15
Data point term sent to Coder	System	22 Aug 2020 15:01:29
User entered 'ALPRAZOLAM'	(b) (4), (b) (6)	22 Aug 2020 15:01:27

FDA-CBER-2022-1614-1772931

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'ANXIETY'	(b) (4), (b) (6)	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '0.5'	(b) (4), (b) (6)	22 Aug 2020 15:01:27

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 15:01:27

FDA-CBER-2022-1614-1772935

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'as needed (PRN)'	(b) (4), (b) (6)	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:01:27

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '01 Mar 2020'	(b) (4), (b) (6)	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:01:27

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 15:03:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 15:03:15
Data point term sent to Coder	System	22 Aug 2020 15:02:29
User entered 'TRAZODONE'	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered 'INSOMNIA'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) ▨ (b) (4)	08 Apr 2021 23:44:07
User entered '50'	(b) (4), (b) (6) ▨	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'as needed (PRN)'	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '01 Mar 2020'	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 15:02:15

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:22:36

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
Signature has been broken.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:28:28
User entered 'Yes (Y)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:28:28
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:44:07
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	22 Aug 2020 16:48:35

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:45:40

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Complete metabolic Profile'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:45:40

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:45:40

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:45:40

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:46:04

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Complete Blood Count'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:46:04

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:46:04

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:46:04

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:04
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:51:11

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:04
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Protime-INR'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:51:11

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:04
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:51:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:04
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:51:11

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:07
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:51:24

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:07
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'APTT'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:51:24

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:07
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:51:24

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:07
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:51:24

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:09
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:52:17

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:09
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'TROPONIN-I' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:56:58
User entered 'Troponin-1'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:52:17

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:09
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:52:17

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:09
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:52:17

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:57:30

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Magnesium'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:57:30

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:57:30

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:57:30

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:12
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:57:47

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:12
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'D-Dimer'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:57:47

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:12
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:57:47

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:12
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:57:47

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:58:25

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Covid 19 Test'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:58:25

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:58:25

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:15
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:58:25

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:58:52

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Chest xray'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:58:52

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:58:52

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 15:58:52

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:17
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 16:01:35

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:17
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Stress test'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 16:01:35

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:17
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 16:01:35

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:17
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 16:01:35

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '23 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 16:05:00

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Echo cardiagram'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 16:05:00

US3402420

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:22:36

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 16:05:00

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:35:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	19 Apr 2021 16:05:00

US3402420
Folder: SAE USA-US059-2021-MRNA-1273-P301000014
Form: Safety Report Form
Generated On: 09 Jun 2021 17:22:36
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'USA-US059-2021-MRNA-1273-P301000014'	System	20 Apr 2021 17:22:42

US3402420
Folder: SAE USA-US059-2021-MRNA-1273-P301000014
Form: Safety Report Form
Generated On: 09 Jun 2021 17:22:36
Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'Yes (Y)'	System	20 Apr 2021 17:22:42

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'No (N)'	System	20 Apr 2021 17:22:42

FDA-CBER-2022-1614-1773014

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'No (N)'	System	20 Apr 2021 17:22:42

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'Yes (Y)'	System	20 Apr 2021 17:22:42

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'No (N)'	System	20 Apr 2021 17:22:42

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'No (N)'	System	20 Apr 2021 17:22:42

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'No (N)'	System	20 Apr 2021 17:22:42

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'Frank'	System	20 Apr 2021 17:22:42

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'Eder'	System	20 Apr 2021 17:22:42

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered '1290 Upper Front Street'	System	20 Apr 2021 17:22:42

US3402420
Folder: SAE USA-US059-2021-MRNA-1273-P301000014
Form: Safety Report Form
Generated On: 09 Jun 2021 17:22:36
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'Binghamton'	System	20 Apr 2021 17:22:42

US3402420
Folder: SAE USA-US059-2021-MRNA-1273-P301000014
Form: Safety Report Form
Generated On: 09 Jun 2021 17:22:36

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'NY'	System	20 Apr 2021 17:22:42

US3402420
Folder: SAE USA-US059-2021-MRNA-1273-P301000014
Form: Safety Report Form
Generated On: 09 Jun 2021 17:22:36

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered '13901'	System	20 Apr 2021 17:22:42

Folder: SAE USA-US059-2021-MRNA-1273-P301000014
Form: Safety Report Form
Generated On: 09 Jun 2021 17:22:36

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'US'	System	20 Apr 2021 17:22:56

US3402420
Folder: SAE USA-US059-2021-MRNA-1273-P301000014
Form: Safety Report Form
Generated On: 09 Jun 2021 17:22:36
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:22:56

Folder: SAE USA-US059-2021-MRNA-1273-P301000014
Form: Safety Report Form
Generated On: 09 Jun 2021 17:22:36

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'USA-US059-2021-MRNA-1273-P301000014'	System	20 Apr 2021 17:22:42

US3402420
Folder: SAE USA-US059-2021-MRNA-1273-P301000014
Form: Safety Report Form
Generated On: 09 Jun 2021 17:22:36
Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'Yes (Y)'	System	20 Apr 2021 17:22:42

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'No (N)'	System	20 Apr 2021 17:22:42

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'No (N)'	System	20 Apr 2021 17:22:42

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'Yes (Y)'	System	20 Apr 2021 17:22:42

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'No (N)'	System	20 Apr 2021 17:22:42

FDA-CBER-2022-1614-1773033

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'No (N)'	System	20 Apr 2021 17:22:42

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'No (N)'	System	20 Apr 2021 17:22:42

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'Frank'	System	20 Apr 2021 17:22:42

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'Eder'	System	20 Apr 2021 17:22:42

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered '1290 Upper Front Street'	System	20 Apr 2021 17:22:42

US3402420
Folder: SAE USA-US059-2021-MRNA-1273-P301000014
Form: Safety Report Form
Generated On: 09 Jun 2021 17:22:36

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'Binghamton'	System	20 Apr 2021 17:22:42

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'NY'	System	20 Apr 2021 17:22:42

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered '13901'	System	20 Apr 2021 17:22:42

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:51:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered 'US'	System	20 Apr 2021 17:22:56

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 17:22:56

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:22:36

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:51:25
User entered '20/Apr/2021 13:22'	System	20 Apr 2021 17:22:56

US3402420

Folder: SAE USA-US059-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:22:36

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)	26 Apr 2021 23:51:25
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 17:22:59
User entered '1'	(b) (4), (b) (6)	20 Apr 2021 17:22:56