US3222004 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:02:02

All time stamps listed in this document are displayed in GMT

Participant ID   US3222004

mRNA-1273-P301 Completion Guidelines

US3222004

Folder: Screening

Form: Visit Date

Data signed: (b) (4)　**16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SCRN

US3222004

Folder: Screening

Form: Demographics

Data signed: (b) (4) **16 Feb 2021 16:25:56**

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Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
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

US3222004

Folder: Screening

Form: Enrollment

Data signed: (b) (4)   **16 Feb 2021 16:25:56**

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Date of Informed Consent *(dd MMM yyyy)*	6 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

US3222004
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **16 Feb 2021 16:25:56**
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Did the participant meet all eligibility criteria?   Yes ●
                                                       No ○

Were any significant conditions reported?   Yes ⬤

                                                                                    No ◯

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	TENSION HEADACHES
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	POSTMENOPAUSAL
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)	

Folder: Screening

Form: Medical History (3)

Data signed: ▓ (b) (4) ▓ **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	DEPRESSION
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)	

US3222004

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	ATRIAL FLUTTER
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

US3222004

Folder: Screening

Form: Medical History (5)

Data signed: ███ (b) (4) ███ **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Start Year (derived)	1977
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4)   **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	COLONOSCOPY
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬭
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3222004

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	DILATION AND CURETTAGE
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3222004

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	EX-SMOKER
Start date (dd MMM yyyy)	UN UNK 1967
Start date completely unknown	False
Condition ongoing at study entry	Yes ⭕
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1975
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1967
Start Year (derived)	1967
Stop Month and Year (derived)	JAN 1975
Stop Year (derived)	1975

US3222004

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 16 Feb 2021 16:25:56

Generated On: 09 Jun 2021 16:02:02

Condition	FIBROMYALGIA
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

US3222004

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	HYPOPARATHYROIDISM
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)	

US3222004

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	INSOMNIA
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)	

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4)   **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	MUSCLE SPASMS
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	OSTEOARTHRITIS
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)	

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	RHINOPLASTY
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3222004

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	ROSACEA
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)	

US3222004

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4)   **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Condition	SLEEP APNEA
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)	

Condition	TENSION HEADACHE
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

Condition	LEVAQUIN 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)	

US3222004
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	06 AUG 2020
Time of assessment *(00:00-23:59)*	08:58 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 08:58
Height *(xxx.x)*	162.5 cm
Weight *(xxx.x)*	63.2 kg
BMI *(xxx.x)*	23.93373 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)	

US3222004

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?   Yes ⬤

No ◯

Date of examination *(dd MMM yyyy)*   06 AUG 2020

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

US3222004

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) **16 Feb 2021 16:25:56**

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Date of assessment *(dd MMM yyyy)*	06 AUG 2020
Is the participant of childbearing potential?	Yes ⭕
	No ⚫
If No, what is the reason?	Surgically sterile ⭕
	Post-menopausal ⚫
	Partner medically sterile ⭕
	Not reached age of Menarche ⭕
	Other ⭕
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	True

US3222004
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) 16 Feb 2021 16:25:56
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Occupational Risk

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

  Specify _____

Location and Living Circumstances Risk (check all that apply)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4)   **16 Feb 2021 16:25:56**

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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	

US3222004
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Was this visit performed?	Yes ⬤
	No ◯
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤
Folder OID	VISIT1

US3222004
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

What was the date of randomization? *(dd MMM yyyy)*	06 AUG 2020
What was the participant's randomization number?	184913

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 ●

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Height	ND - Not Done
Weight	ND - Not Done

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

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)*	06 AUG 2020
Time of assessment *(00:00-23:59)*	08:58 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 08:58
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

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)*	06 AUG 2020
Time of assessment *(00:00-23:59)*	10:35 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 10:35
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	94 mmHg
Diastolic Blood Pressure units	MMHG

US3222004
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?   Yes ●

                                                                              No ◯

Date of examination *(dd MMM yyyy)*   06 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)*	6 AUG 2020
What was the treatment time? *(00:00-23:59)*	09:58 (24 HR)
Treatment Date and Time (derived)	6 AUG 2020 09:58

Which arm was used to give treatment?   Left Arm ⬤

Right Arm ◯

What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	06 AUG 2020
Collection time *(00:00-23:59)*	09:15 (24 HR)
Collection date and time (derived)	06 AUG 2020 09:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Collection date *(dd MMM yyyy)*			06 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:18	06 AUG 2020 09:18
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

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**	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	06 AUG 2020 10:33
PC Open Date & Time	06 AUG 2020 10:18
PC Close Date & Time	06 AUG 2020 12:48

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02

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	06 AUG 2020 21:13
PC Open Date & Time	06 AUG 2020 13:43
PC Close Date & Time	07 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.5 °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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	07 AUG 2020 21:02
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	08 AUG 2020 20:50
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02

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**	97.7 °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	09 AUG 2020 20:01
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ◯
	No ◯
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ◯
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.3 °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	11 AUG 2020 21:43
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-3552404

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ◯
	No ◯
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ◯
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:02:02

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	06 AUG 2020 10:32
PC Open Date & Time	06 AUG 2020 10:18
PC Close Date & Time	06 AUG 2020 12:48

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:02:02

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	06 AUG 2020 21:15
PC Open Date & Time	06 AUG 2020 13:43
PC Close Date & Time	07 AUG 2020 11:59

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	07 AUG 2020 21:03
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 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	08 AUG 2020 20:51
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3222004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

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	09 AUG 2020 20:02
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02

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 ◯

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

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

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

- Yes ◯
- No ◯

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

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

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
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	_____
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02

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	11 AUG 2020 21:43
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02

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 ◯

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

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

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

- Yes ◯
- No ◯

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

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

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
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	_____
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02

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	◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	06 AUG 2020 10:34
PC Open Date & Time	06 AUG 2020 10:18
PC Close Date & Time	06 AUG 2020 12:48

FDA-CBER-2022-1614-3552415

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02

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	06 AUG 2020 21:16
PC Open Date & Time	06 AUG 2020 13:43
PC Close Date & Time	07 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02

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	07 AUG 2020 21:05
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02

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	08 AUG 2020 20:52
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-3552421

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02

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	09 AUG 2020 20:02
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 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-2022-1614-3552424

	Yes ◯
PC Time stamp	
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02

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 ◯

	Yes ◯
PC Time stamp	
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 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 ◯

Yes ◯

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

US3222004
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?   Yes ⬤

No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*   13 AUG 2020

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

Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3222004

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?   Yes ⬤

                                                                                     No ◯

Continuing Flag   1

US3222004
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	20 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○
Comments	NO AE'S OR CHANGES NOTED OR EXPRESSED. DENIES COVID-19 SYMPTOMS. NO CONMED CHANGES OR VACCINES.
If Contact Not Made, please provide Comments	

Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3222004
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 27 AUG 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3222004
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?   Yes ●
                                                                                    No ○

Continuing Flag   1

US3222004
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ●
	Clinic ○
Folder OID	VISIT2

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	10 SEP 2020
Time of assessment *(00:00-23:59)*	14:38 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 14:38
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	83 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG

Timepoint	Pre-Dose ⚪
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⚪
Date of assessment *(dd MMM yyyy)*	10 SEP 2020
Time of assessment *(00:00-23:59)*	15:56 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 15:56
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ⬤
	Axillary ⚪
	Other ⚪
If Other, specify	
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	86 mmHg
Diastolic Blood Pressure units	MMHG

US3222004

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?   Yes ●

                                                            No ○

Date of examination *(dd MMM yyyy)*   10 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)*	10 SEP 2020
What was the treatment time? *(00:00-23:59)*	15:25 (24 HR)
Treatment Date and Time (derived)	10 SEP 2020 15:25
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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

Collection date *(dd MMM yyyy)*	10 SEP 2020
Collection time *(00:00-23:59)*	14:51 (24 HR)
Collection date and time (derived)	10 SEP 2020 14:51

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Collection date *(dd MMM yyyy)*			10 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:58	10 SEP 2020 14:58
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-3552442

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**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	10 SEP 2020 16:00
PC Open Date & Time	10 SEP 2020 15:45
PC Close Date & Time	10 SEP 2020 18:15

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**	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	11 SEP 2020 04:50
PC Open Date & Time	10 SEP 2020 19:10
PC Close Date & Time	11 SEP 2020 11:59

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02

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**	100.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	11 SEP 2020 22:00
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

TIMEPOINT	DAY 3

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	98.8 °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	12 SEP 2020 21:48
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ⬤
	No ◯
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ⬤

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	13 SEP 2020 21:27
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	14 SEP 2020 22:12
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ⬤
	No ◯
Please record your **TEMPERATURE in °F**	97.7 °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	15 SEP 2020 21:53
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	16 SEP 2020 22:38
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:02:02

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	10 SEP 2020 16:01
PC Open Date & Time	10 SEP 2020 15:45
PC Close Date & Time	10 SEP 2020 18:15

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:02:02

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	11 SEP 2020 04:51
PC Open Date & Time	10 SEP 2020 19:10
PC Close Date & Time	11 SEP 2020 11:59

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02

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	11 SEP 2020 22:00
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:02:02

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	12 SEP 2020 21:49
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.**	None ◯
Please select one response below	Does not interfere with activity ⬤
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**	None ⬤
Please select one response below	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	13 SEP 2020 21:27
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3222004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

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	14 SEP 2020 22:12
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 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	15 SEP 2020 21:54
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

FDA-CBER-2022-1614-3552458

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	16 SEP 2020 22:39
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02

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 ⬭

FDA-CBER-2022-1614-3552460

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02

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

PC Time stamp	
PC Open Date & Time	10 SEP 2020 15:45
PC Close Date & Time	10 SEP 2020 18:15

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02

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	11 SEP 2020 04:55
PC Open Date & Time	10 SEP 2020 19:10
PC Close Date & Time	11 SEP 2020 11:59

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	11 SEP 2020 22:01
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02

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	12 SEP 2020 21:50
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

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

FDA-CBER-2022-1614-3552468

	Yes ◯
PC Time stamp	13 SEP 2020 21:28
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 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 ●

	Yes ◯
PC Time stamp	14 SEP 2020 22:13
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02

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 ⬤

	Yes ◯
PC Time stamp	15 SEP 2020 21:54
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 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 ●

FDA-CBER-2022-1614-3552474

	Yes ◯
PC Time stamp	16 SEP 2020 22:41
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3222004

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 17 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3222004

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4)   **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?   Yes ●

                                                                                     No ○

Continuing Flag   1

US3222004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 24 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3222004

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3222004
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?   Yes ●

                                                                            No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*   1 OCT 2020

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

                                                            Contact Not Made ○

Comments

If Contact Not Made, please provide Comments   _____

US3222004
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3222004
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT3

US3222004
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4)   **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

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)   _____

US3222004

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

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.

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

Collection date *(dd MMM yyyy)*	08 OCT 2020
Collection time *(00:00-23:59)*	14:15 (24 HR)
Collection date and time (derived)	08 OCT 2020 14:15

US3222004

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ◯

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ◯

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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-2022-1614-3552491

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 19:45:54
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-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 NOV 2020 16:50:15
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-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 NOV 2020 12:15:19
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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	25 NOV 2020 08:10:18
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ●
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 09:19:18
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 14:59:07
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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	28 DEC 2020 12:21:04
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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	04 JAN 2021 08:48:33
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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	09 JAN 2021 09:07:22
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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	24 JAN 2021 19:40:16
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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	02 FEB 2021 19:41:04
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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	06 FEB 2021 19:01:38
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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	13 FEB 2021 09:30:28
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

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	23 FEB 2021 08:40:50
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 21:17:47
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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	08 MAR 2021 08:57:22
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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 ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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	13 MAR 2021 10:45:22
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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	22 MAR 2021 08:05:44
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3222004

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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	29 MAR 2021 09:29:10
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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	03 APR 2021 09:31:20
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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	11 APR 2021 09:25:32
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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	17 APR 2021 21:58:27
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 APR 2021 14:21:30
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

TIMEPOINT   DAY 271

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

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

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 ⭕

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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):

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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 285

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

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

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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):

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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	**DAY 299**

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

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

Fever (Temperature ≥ 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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

TIMEPOINT   DAY 306

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT   DAY 313

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-3552534

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ⭕

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT   DAY 327

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT   **DAY 334**

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

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

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

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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):

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	◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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-2022-1614-3552544

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

<table>
<tr><td>TIMEPOINT</td><td align="right">DAY 355</td></tr>
</table>

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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-2022-1614-3552548

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT   DAY 376

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-3552552

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT   DAY 383

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	**DAY 390**

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-3552556

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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):

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-2022-1614-3552558

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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):	
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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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-2022-1614-3552562

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ⭕

FDA-CBER-2022-1614-3552564

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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-2022-1614-3552566

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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):

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 ⚪ |

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 $\geq$ 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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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):

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-2022-1614-3552574

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ⚪

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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):

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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

TIMEPOINT	**DAY 474**

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

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

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-2022-1614-3552580

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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):

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-2022-1614-3552582

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ⬭

FDA-CBER-2022-1614-3552588

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ≥ 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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT DAY 516

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

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

Fever (Temperature ≥ 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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ⭕

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	**DAY 530**

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ⬭ |

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	**DAY 537**

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-3552598

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	**DAY 544**

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ⭕

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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):

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-2022-1614-3552604

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ≥ 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 ⟲

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT DAY 586

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-3552612

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

TIMEPOINT	**DAY 593**

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

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

Fever (Temperature $\geq$ 100.4°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-2022-1614-3552614

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 $\geq$ 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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT   DAY 607

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ⬭

FDA-CBER-2022-1614-3552620

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	**DAY 621**

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 628

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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):

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 ⭕

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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):

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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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-2022-1614-3552630

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 656

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT   DAY 663

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

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

Fever (Temperature ≥ 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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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):

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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT   DAY 698

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

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

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

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	**DAY 705**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT   DAY 712

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

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

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

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	**DAY 726**

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 JUL 2022 00:01
Patient Cloud Close Date & Time	03 AUG 2022 23:59

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ≥ 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-2022-1614-3552654

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 $\geq$ 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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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):

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 ⬭

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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 ≥ 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-2022-1614-3552662

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

TIMEPOINT   DAY 768

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

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

Fever (Temperature $\geq$ 100.4°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 ◯

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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):

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 ○

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT **DAY 782**

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

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

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 ◯

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	**DAY 789**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

Fever (Temperature $\geq$ 100.4°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 ⭕

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 ≥ 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 ⭕

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

US3222004

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:02:02

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 21:18:03

US3222004
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 16:25:56**
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?   Yes ●

                                                                          No ○

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

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

                                                       Contact Not Made ○

Comments

If Contact Not Made, please provide Comments _____

US3222004

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?   Yes ⬤

                                                                                     No ◯

Continuing Flag   1

US3222004
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 16:25:55**
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	08 DEC 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3222004

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 16:25:55**

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3222004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 16:25:56**

Generated On: 09 Jun 2021 16:02:02

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 05 JAN 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3222004

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 16:25:55**

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?   Yes ⬤

                                                                                     No ◯

Continuing Flag   1

US3222004
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **25 Mar 2021 17:10:02**
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*   04 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3222004

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **25 Mar 2021 17:10:02**

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?   Yes ●

                      No ○

Continuing Flag   1

Data signed: (b) (4) **25 Mar 2021 17:10:02**
Generated On: 09 Jun 2021 16:02:02

Was this visit performed?	Yes ⬤
	No ◯
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤
Folder OID	VISIT4

US3222004
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **05 Apr 2021 20:09:26**
Generated On: 09 Jun 2021 16:02:02

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)	_____

US3222004

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **25 Mar 2021 17:10:02**

Generated On: 09 Jun 2021 16:02:02

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.

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	15 MAR 2021
Collection time *(00:00-23:59)*	12:40 (24 HR)
Collection date and time (derived)	15 MAR 2021 12:40

Form: Continuing
Data signed: (b) (4) **25 Mar 2021 17:10:02**
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3222004
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **05 Apr 2021 20:09:26**
Generated On: 09 Jun 2021 16:02:02

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 05 APR 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3222004

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **05 Apr 2021 20:09:26**

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3222004
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

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

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 ◯

Generate Next COVID-19 Assessment	Yes ◯
	No ◯

Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **16 Feb 2021 16:25:55**
Generated On: 09 Jun 2021 16:02:02

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	17 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-3552694

US3222004

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

Form: Unblinding

Data signed: [(b) (4)] **26 Apr 2021 13:33:39**

Generated On: 09 Jun 2021 16:02:02

Date of updated informed consent *(dd MMM yyyy)*	17 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)*	17 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	
Continuing with mRNA-1273	

Was the sample collected?	Yes	⬤
	No	◯

Collection date *(dd MMM yyyy)*	17 JAN 2021
Collection time *(00:00-23:59)*	7:55 (24 HR)
Collection date and time (derived)	17 JAN 2021 7:55

US3222004

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **16 Feb 2021 16:25:54**

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?	Yes ●
	No ◯
Collection date *(dd MMM yyyy)*	17 JAN 2021
Collection time *(00:00 - 23:59)*	7:58
Collection Date and Time (derived)	17 JAN 2021 7:58

US3222004
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **16 Feb 2021 16:25:54**
Generated On: 09 Jun 2021 16:02:02

Did the participant experience any adverse events?   Yes ●

No ◯

If Yes, enter details on the Adverse Events form.

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **25 Mar 2021 17:10:02**

Generated On: 09 Jun 2021 16:02:02

AEID	USA-US104-2020-MRNA-1273-P30 1000011
Adverse event	UNCONTROLLED HYPERTENSION

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)*	1 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	2 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

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

Is the adverse event serious? Yes ● No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	1 OCT 2020
Hospital Discharge Date *(dd MMM yyyy)*	2 OCT 2020

Admitted to ICU? Yes ○ No ● Unknown ○

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

FDA-CBER-2022-1614-3552700

THIS SAE WAS SUBMITTED THE SAME DAY 05/OCT/2020 VIA EMAIL.
PATIENT CALLED ME TODAY 05/OCT/2020 @ 13:01 TO TELL ME SHE WAS IN THE HOSPITAL FOR HYPERTENSION. ADMISSION 01/OCT/2020 FOR CHEST PRESSURE WITH ELEVATED BLOOD PRESSURE. HER TROPONINS WERE NEGATIVE, SHE HAD A 2D ECHO, AND STRESS TEST AND SHE WAS PRESCRIBED LOSARTAN 25 MG AT DISCHARGE. SHE WILL FOLLOW-UP WITH HER PCP (WHOM IS OUR SUB-I ON THIS TRIAL) IN 1-2 WEEKS.

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

FDA-CBER-2022-1614-3552701

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **16 Feb 2021 16:25:54**

Generated On: 09 Jun 2021 16:02:02

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

    No ○

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **22 Feb 2021 15:48:02**

Generated On: 09 Jun 2021 16:02:02

Name of Medication	IBUPROFEN

Prophylaxis	Yes ●
	No ○

Indication	HEADACHES
Dose per administration	400

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)*	
Start date completely unknown	True
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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: ▨ (b) (4) ▨ **22 Feb 2021 15:48:02**

Generated On: 09 Jun 2021 16:02:02

Name of Medication	LOSARTAN

Prophylaxis	
	Yes ◯
	No ⬤

Indication	HYPERTENSION
Dose per administration	50

Dose unit	
	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯

If dose unit is Other, specify _____

Frequency	
	once daily ⬤
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯

If frequency is Other, specify _____

Route of administration	
	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

PRODUCTION RELEASE (v12.003
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)*	2 OCT 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 ●

Name of Medication	HYDROCODONE

Prophylaxis	Yes ⚪
	No ⚫

Indication	FIBROMYALGIA

Dose per administration	5

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration	Oral ⚫
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

	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 2005

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 ◯

Name of Medication	LEVOTHYROXINE

Prophylaxis

Yes ⚪
No ⬤

Indication	HYPOPARATHYROIDISM
Dose per administration	100

Dose unit

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

If dose unit is Other, specify

Frequency

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

If frequency is Other, specify

Route of administration

Oral ⬤
Topical ⚪
Subcutaneous ⚪
Transdermal ⚪
Intraocular ⚪

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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 2015

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 (5)

Data signed: (b) (4) **22 Feb 2021 15:48:02**

Generated On: 09 Jun 2021 16:02:02

Name of Medication	LIOTHYRONINE
Prophylaxis	Yes ○
	No ●
Indication	HYPOPARATHYROIDISM
Dose per administration	25
Dose unit	mg ○
	ug ●
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ●
If frequency is Other, specify	MON/WED/FRI
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **22 Feb 2021 15:48:02**
Generated On: 09 Jun 2021 16:02:02

	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 2010
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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: ▨ (b) (4) ▨ **22 Feb 2021 15:48:02**

Generated On: 09 Jun 2021 16:02:02

Name of Medication	MELOXICAM

Prophylaxis	
	Yes ◯
	No ●

Indication	FIBROMYALGIA

Dose per administration	7.5

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)*   UN UNK 2000

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 ⬤

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Name of Medication	NORTRIPTYLINE

Prophylaxis	Yes ⚪
	No ⚫

Indication	MUSCLE SPASMS

Dose per administration	25

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

If dose unit is Other, specify	_____

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

If frequency is Other, specify	_____

Route of administration	Oral ⚫
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

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 2005
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 (8)

Data signed: (b) (4) **22 Feb 2021 15:48:02**

Generated On: 09 Jun 2021 16:02:02

Name of Medication	ORACEA
Prophylaxis	Yes ◯
	No ⬤

Indication	ROSACEA
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 2005
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) ▢ **22 Feb 2021 15:48:02**

Generated On: 09 Jun 2021 16:02:02

Name of Medication	TIZANIDINE
Prophylaxis	Yes ◯
	No ⬤
Indication	MUSCLE SPASMS
Dose per administration	4
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 2005
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 ◯

FDA-CBER-2022-1614-3552720

Name of Medication	TRAMADOL

Prophylaxis	Yes ○
	No ●

Indication	FIBROMYALGIA
Dose per administration	100

Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify	

Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ●
	once ○
	unknown ○
	other ○

If frequency is Other, specify	

Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

	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 2010
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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4)   **22 Feb 2021 15:48:02**

Generated On: 09 Jun 2021 16:02:02

Name of Medication	VENLAFAXINE

Prophylaxis

Yes ◯

No ⬤

Indication	DEPRESSION OVER FIBROMYALGIA
Dose per administration	37.5

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)*	UN UNK 2000
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 ⬤

Name of Medication	MULTIVITAMIN

Prophylaxis

Yes ●

No ○

Indication	SUPPLEMENT
Dose per administration	1

Dose unit

mg ○
ug ○
mL ○
g ○
IU ○
tablet ●
capsule ○
puff ○
Other ○

If dose unit is Other, specify _____

Frequency

once daily ●
twice daily ○
three times daily ○
four times daily ○
every other day ○
every week ○
every month ○
as needed ○
once ○
unknown ○
other ○

If frequency is Other, specify _____

Route of administration

Oral ●
Topical ○
Subcutaneous ○
Transdermal ○
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)* _____

Start date completely unknown   True

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 (13)

Data signed: (b) (4)   **22 Feb 2021 15:48:02**

Generated On: 09 Jun 2021 16:02:02

Name of Medication	OMEGA 3
Prophylaxis	Yes ●
	No ○
Indication	SUPPLEMENT
Dose per administration	1200
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 (13)
Data signed: (b) (4) **22 Feb 2021 15:48:02**
Generated On: 09 Jun 2021 16:02:02

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)*	
Start date completely unknown	True
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 (14)

Data signed: (b) (4) **22 Feb 2021 15:48:02**

Generated On: 09 Jun 2021 16:02:02

Name of Medication	INFLUENZA VACCINE

Prophylaxis	Yes ●
	No ○

Indication	INFLUENZA
Dose per administration	1

Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●

If dose unit is Other, specify	UNK

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)*	24 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	24 SEP 2020
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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) **22 Feb 2021 15:48:02**

Generated On: 09 Jun 2021 16:02:02

Name of Medication	GLUCOSAMINE CHONDROITIN WITH MSM

Prophylaxis	Yes	●
	No	○

Indication	CARTILAGE SUPPORT - PROPHYLAXIS.

Dose per administration	1

Dose unit	mg	○
	ug	○
	mL	○
	g	○
	IU	○
	tablet	○
	capsule	●
	puff	○
	Other	○

If dose unit is Other, specify	

Frequency	once daily	○
	twice daily	○
	three times daily	●
	four times daily	○
	every other day	○
	every week	○
	every month	○
	as needed	○
	once	○
	unknown	○
	other	○

If frequency is Other, specify	

Route of administration	Oral	●
	Topical	○
	Subcutaneous	○
	Transdermal	○

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	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)*	03 FEB 2021
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)	3
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 (17)

Data signed: (b) (4) **22 Feb 2021 15:48:02**

Generated On: 09 Jun 2021 16:02:02

Name of Medication	LOSARTAN

Prophylaxis	Yes ⚪
	No ⚫

Indication	HYPERTENSION
Dose per administration	50

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

Route of administration	Oral ⚫
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

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)*	06 JAN 2021
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 ⬤

US3222004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **16 Feb 2021 16:25:54**

Generated On: 09 Jun 2021 16:02:02

Were any concomitant procedures performed?   Yes ●

                                                                               No ○

If yes, please complete Concomitant Procedures form.

US3222004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **16 Feb 2021 16:25:54**

Generated On: 09 Jun 2021 16:02:02

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
01 OCT 2020	2D ECHO	Adverse Event	
01 OCT 2020	STRESS TEST	Adverse Event	
01 OCT 2020	BLOOD WORK FOR TROPONINS	Adverse Event	

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	◯

FDA-CBER-2022-1614-3552738

SAEID	USA-US104-2020-MRNA-1273-P30 1000011
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	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

SAEID	USA-US104-2020-MRNA-1273-P30 1000011
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	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/OCT/2020 10:10
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

SAEID	USA-US104-2020-MRNA-1273-P30 1000011
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	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/OCT/2020 18:53
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

SAEID	USA-US104-2020-MRNA-1273-P30 1000011
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	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/OCT/2020 16:53
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

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form (4)
Data signed: (b) (4) **25 Mar 2021 17:10:02**
Generated On: 09 Jun 2021 16:02:02

SAEID	USA-US104-2020-MRNA-1273-P30 1000011
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	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/DEC/2020 15:23
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

US3222004

Folder: SAE USA-US104-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) **25 Mar 2021 17:10:02**

Generated On: 09 Jun 2021 16:02:02

SAEID	USA-US104-2020-MRNA-1273-P30 1000011
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	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	05/MAR/2021 11:30
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

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form (6)
Data signed: (b) (4) **25 Mar 2021 17:10:02**
Generated On: 09 Jun 2021 16:02:02

SAEID	USA-US104-2020-MRNA-1273-P30 1000011
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	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/MAR/2021 09:21
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

US3222004 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222004
Form: Participant Creation
Generated On: 09 Jun 2021 16:02:02
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'US3222004'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 13:04:50

Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:06
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:18:46

FDA-CBER-2022-1614-3552748

US3222004
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:06
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 13:04:51

US3222004
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:18
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:06
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	06 Aug 2020 14:18:46
	(b) (4)	

US3222004
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'SCRN'	System	06 Aug 2020 14:18:46

US3222004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered (b) (6) 1951'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 13:04:52

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered '69'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:25:51

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'YEARS'	System	06 Aug 2020 15:25:51

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '69'	System	06 Aug 2020 14:19:03

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered 'Female (F)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:25:51

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:25:51

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered '1'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:25:51

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered '0'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:25:51

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered '0'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:25:51

US3222004

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered '0'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:25:51

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered '0'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:25:51

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered '0'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:25:51

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered empty.	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:25:51

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered '0'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:25:51

US3222004
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 16:02:02
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:10
User entered '0'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:25:51

US3222004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:58
User entered '6 Aug 2020'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:03

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Aug 2020'	System	06 Aug 2020 14:19:03

US3222004
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:02:02
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '2020'	System	06 Aug 2020 14:19:03

US3222004
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:02:02
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:58
User entered 'Amendment 1 (1)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:03

US3222004
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:02:02
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:58
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:03

US3222004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:58
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:03

US3222004

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:58
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:03

US3222004
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:02:02

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:58
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:03

US3222004
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:02:02
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:58
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 13:04:51

US3222004
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 16:02:02
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1'	System	06 Aug 2020 14:19:12

US3222004

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:02:02

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:17
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:12

US3222004
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 16:02:02
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:20
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:26
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:28:38

US3222004
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:23
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Tension headache, LLT: Tension headaches - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 21:17:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 21:17:49
Data point term sent to Coder	System	23 Aug 2020 21:17:06
Coding entries removed.	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:16:53
User entered 'TENSION HEADACHES' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:16:53
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 21:10:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 21:10:47
Data point term sent to Coder	System	23 Aug 2020 21:10:04
User entered 'Headaches'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:09:08

US3222004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:23
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Aug 2020 21:17:23
User entered 'UN UNK 1980' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:17:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Aug 2020 21:16:53
User entered ' 1980' (non-conformant).	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:16:53
User entered empty.	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:09:08

FDA-CBER-2022-1614-3552780

US3222004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:23
User entered '0' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:17:06
User entered '1'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:09:08

US3222004
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:02:02
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:23
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:09:08

US3222004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:23
User entered empty.	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:09:08

US3222004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:23
User entered '0'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:09:08

US3222004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 1980'	System	23 Aug 2020 21:17:23
User entered empty.	System	23 Aug 2020 21:09:08

US3222004

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1980'	System	23 Aug 2020 21:17:23
User entered empty.	System	23 Aug 2020 21:09:08

US3222004
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:02:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	23 Aug 2020 21:09:08

Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 16:02:02

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	23 Aug 2020 21:09:08

US3222004
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:50:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:50:15
Data point term sent to Coder	System	27 Aug 2020 18:49:21
User entered 'Postmenopausal'	Amber Vasquez (b) (4) (b) (4)	27 Aug 2020 18:49:21

US3222004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 2010' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:38:06
User entered empty.	Amber Vasquez (b) (4) (b) (4)	27 Aug 2020 18:49:21

US3222004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:38:06
User entered '1'	Amber Vasquez (b) (4) (b) (4)	27 Aug 2020 18:49:21

US3222004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	27 Aug 2020 18:49:21

US3222004

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	Amber Vasquez (b) (4) (b) (4)	27 Aug 2020 18:49:21

US3222004
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:02:02
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	Amber Vasquez (b) (4) (b) (4)	27 Aug 2020 18:49:21

US3222004
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 2010'	System	30 Oct 2020 17:38:06
User entered empty.	System	27 Aug 2020 18:49:21

US3222004
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '2010'	System	30 Oct 2020 17:38:06
User entered empty.	System	27 Aug 2020 18:49:21

US3222004
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:02:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	27 Aug 2020 18:49:21

US3222004
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	27 Aug 2020 18:49:21

US3222004
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:28:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:28:57
Data point term sent to Coder	System	30 Oct 2020 17:28:29
User entered 'DEPRESSION'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:28:06

US3222004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 2000'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:28:06

US3222004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:28:06

US3222004
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:02:02
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:28:06

Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:28:06

US3222004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:28:06

US3222004
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 2000'	System	30 Oct 2020 17:28:06

US3222004

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '2000'	System	30 Oct 2020 17:28:06

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:28:06

US3222004
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:28:06

US3222004
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query 'Per CDM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 11:49:32
Query 'Per CDM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'confirmed no con med for atrial flutter' (Site from DM).	gail lavine (b) (4) (b) (4)	13 Jan 2021 14:23:52
User opened query 'Per CDM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 02:57:13
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Atrial flutter - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:39:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:39:02
Data point term sent to Coder	System	30 Oct 2020 17:38:40
User entered 'ATRIAL FLUTTER'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:38:39

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US3222004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 1960'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:38:39

US3222004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:38:39

US3222004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:38:39

US3222004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:38:39

US3222004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:38:39

US3222004
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 1960'	System	30 Oct 2020 17:38:39

US3222004

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1960'	System	30 Oct 2020 17:38:39

US3222004
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:02:02

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:38:39

US3222004
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:38:39

US3222004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:40:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:40:54
Data point term sent to Coder	System	30 Oct 2020 17:39:41
User entered 'CESAREAN SECTION'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:39:04

US3222004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 1977'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:39:04

US3222004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4)	30 Oct 2020 17:39:04

US3222004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:39:04

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:39:04

FDA-CBER-2022-1614-3552823

US3222004

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:39:04

US3222004
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 1977'	System	30 Oct 2020 17:39:04

US3222004
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1977'	System	30 Oct 2020 17:39:04

US3222004
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 16:02:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:39:04

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:39:04

US3222004
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
Query 'Per CDM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 02:59:04
User opened query 'Per CDM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 02:58:05
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:40:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:40:55
Data point term sent to Coder	System	30 Oct 2020 17:39:41
User entered 'COLONOSCOPY'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:39:36

US3222004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 2016'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:39:36

US3222004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:39:36

US3222004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query 'Per CDM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 14:25:09
Query 'Per CDM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'corrected' (Site from DM).	gail lavine (b) (4) (b) (4)	13 Jan 2021 14:24:54
DataPoint Un-verified.	gail lavine (b) (4) (b) (4)	13 Jan 2021 14:24:42
User entered 'No (N)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	13 Jan 2021 14:24:42
User opened query 'Per CDM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 02:58:41
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:39:36

US3222004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Un-verified.	gail lavine (b) (4) (b) (4)	13 Jan 2021 14:24:42
User entered 'un UNK 2016' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	13 Jan 2021 14:24:42
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:39:36

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US3222004
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:02:02
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:39:36

US3222004

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 2016'	System	30 Oct 2020 17:39:36

US3222004
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '2016'	System	30 Oct 2020 17:39:36

US3222004
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:02:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 2016'	System	13 Jan 2021 14:24:42
User entered empty.	System	30 Oct 2020 17:39:36

US3222004
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '2016'	System	13 Jan 2021 14:24:42
User entered empty.	System	30 Oct 2020 17:39:36

US3222004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Uterine dilation and curettage, LLT: Uterine dilation and curettage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:41:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:41:59
Data point term sent to Coder	System	30 Oct 2020 17:40:42
User entered 'DILATION AND cURETTAGE'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:40:03

US3222004
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:02:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 1995'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:40:03

FDA-CBER-2022-1614-3552840

US3222004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4)	30 Oct 2020 17:40:03

US3222004
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:02:02
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:40:03

US3222004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:40:03

US3222004

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:40:03

US3222004
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 1995'	System	30 Oct 2020 17:40:03

US3222004
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1995'	System	30 Oct 2020 17:40:03

US3222004
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:02:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:40:03

US3222004
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:40:03

US3222004

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Ex-tobacco user, LLT: Ex-smoker - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:43:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:43:00
Data point term sent to Coder	System	30 Oct 2020 17:41:42
User entered 'EX-SMOKER'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:40:57

US3222004

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 1967'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:40:57

US3222004
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:02:02
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:40:57

US3222004
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:02:02
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:40:57

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 1975'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:40:57

US3222004

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:40:57

US3222004
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 1967'	System	30 Oct 2020 17:40:57

US3222004
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1967'	System	30 Oct 2020 17:40:57

US3222004
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:02:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 1975'	System	30 Oct 2020 17:40:57

US3222004
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1975'	System	30 Oct 2020 17:40:57

US3222004
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:44:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:44:10
Data point term sent to Coder	System	30 Oct 2020 17:42:43
User entered 'FIBROMYALGIA'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:41:48

US3222004

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 1980'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:41:48

US3222004

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:41:48

US3222004

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:41:48

US3222004

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:41:48

US3222004

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:41:48

US3222004
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 1980'	System	30 Oct 2020 17:41:48

US3222004
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1980'	System	30 Oct 2020 17:41:48

Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:02:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:41:48

US3222004
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:41:48

US3222004
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Endocrine disorders, HLGT: Parathyroid gland disorders, HLT: Hypoparathyroid disorders, PT: Hypoparathyroidism, LLT: Hypoparathyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:44:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:44:10
Data point term sent to Coder	System	30 Oct 2020 17:42:43
User entered 'HYPOPARATHYROIDISM'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:42:26

US3222004
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:02:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:18
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 2000'	douglas winter (b) (4)	30 Oct 2020 17:42:26
	(b) (4)	

FDA-CBER-2022-1614-3552870

US3222004

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:42:26

US3222004
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:02:02
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:42:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:42:26

FDA-CBER-2022-1614-3552873

US3222004
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:02:02
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:42:26

US3222004

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 2000'	System	30 Oct 2020 17:42:26

US3222004
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '2000'	System	30 Oct 2020 17:42:26

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:42:26

US3222004
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:42:26

US3222004

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
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.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:44:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:44:14
Data point term sent to Coder	System	30 Oct 2020 17:43:44
User entered 'INSOMNIA'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:42:55

FDA-CBER-2022-1614-3552879

US3222004
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:02:02
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 2000'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:42:55

US3222004

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:42:55

US3222004

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:02:02

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:42:55

US3222004

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:42:55

US3222004

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4)	30 Oct 2020 17:42:55

US3222004
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 2000'	System	30 Oct 2020 17:42:55

Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '2000'	System	30 Oct 2020 17:42:55

US3222004
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:02:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:42:55

US3222004
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:42:55

US3222004
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:44:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:44:14
Data point term sent to Coder	System	30 Oct 2020 17:43:44
User entered 'MUSCLE SPASMS'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:43:20

US3222004

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 1970'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:43:20

US3222004

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:43:20

US3222004
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 16:02:02
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:43:20

US3222004

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:43:20

US3222004

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:43:20

US3222004
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 1970'	System	30 Oct 2020 17:43:20

US3222004
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1970'	System	30 Oct 2020 17:43:20

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:43:20

US3222004
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:43:20

US3222004
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:46:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:46:57
Data point term sent to Coder	System	30 Oct 2020 17:45:47
User entered 'OSTEOARTHRITIS'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:20

US3222004

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 2000'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:20

US3222004

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:20

US3222004

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:02:02

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:20

US3222004

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:20

US3222004
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 16:02:02
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:20

US3222004
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 2000'	System	30 Oct 2020 17:45:20

US3222004

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '2000'	System	30 Oct 2020 17:45:20

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:45:20

US3222004
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:45:20

US3222004
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Rhinoplasty, LLT: Rhinoplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:46:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:46:59
Data point term sent to Coder	System	30 Oct 2020 17:45:48
User entered 'RHINOPLASTY'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:39

US3222004

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 1995'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:39

US3222004

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4)	30 Oct 2020 17:45:39

FDA-CBER-2022-1614-3552911

US3222004

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:02:02

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query 'Per CDM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 14:25:41
Query 'Per CDM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'corrected' (Site from DM).	gail lavine (b) (4) (b) (4)	13 Jan 2021 14:25:56
DataPoint Un-verified.	gail lavine (b) (4) (b) (4)	13 Jan 2021 14:25:46
User entered 'No (N)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	13 Jan 2021 14:25:46
User opened query 'Per CDM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 03:05:44
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:39

US3222004

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Un-verified.	gail lavine (b) (4) (b) (4)	13 Jan 2021 14:25:46
User entered 'un UNK 1995' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	13 Jan 2021 14:25:46
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:39

US3222004

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:39

US3222004
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 1995'	System	30 Oct 2020 17:45:39

US3222004
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1995'	System	30 Oct 2020 17:45:39

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 1995'	System	13 Jan 2021 14:25:46
User entered empty.	System	30 Oct 2020 17:45:39

US3222004
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1995'	System	13 Jan 2021 14:25:46
User entered empty.	System	30 Oct 2020 17:45:39

US3222004
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:47:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:47:56
Data point term sent to Coder	System	30 Oct 2020 17:46:49
User entered 'ROSACEA'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:59

US3222004

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 2000'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:59

US3222004

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:59

US3222004

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:02:02

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:59

US3222004

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:59

FDA-CBER-2022-1614-3552923

US3222004
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 16:02:02
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:45:59

US3222004
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 2000'	System	30 Oct 2020 17:45:59

US3222004
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '2000'	System	30 Oct 2020 17:45:59

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:45:59

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:45:59

US3222004
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:47:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:47:56
Data point term sent to Coder	System	30 Oct 2020 17:46:50
User entered 'SLEEP APNEA'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:46:19

US3222004

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 2005'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:46:19

US3222004
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 16:02:02
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:46:19

US3222004

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:02:02

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:46:19

US3222004

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:46:19

US3222004

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:46:19

US3222004
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 2005'	System	30 Oct 2020 17:46:19

US3222004
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '2005'	System	30 Oct 2020 17:46:19

US3222004
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 16:02:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:46:19

US3222004
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:46:19

US3222004
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Tension headache, LLT: Tension headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:47:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:47:55
Data point term sent to Coder	System	30 Oct 2020 17:46:50
User entered 'TENSION HEADACHE'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:46:47

US3222004

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 1980'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:46:47

US3222004
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 16:02:02
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:46:47

US3222004
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 16:02:02
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:46:47

US3222004

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:46:47

US3222004

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:46:47

US3222004
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 1980'	System	30 Oct 2020 17:46:47

US3222004
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1980'	System	30 Oct 2020 17:46:47

US3222004
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 16:02:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:46:47

US3222004
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:46:47

US3222004
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 16:02:02
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
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: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:48:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:48:55
Data point term sent to Coder	System	30 Oct 2020 17:47:52
User entered 'LEVAQUIN ALLERGY'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:47:29

US3222004

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'UN UNK 2005'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:47:29

US3222004

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:47:29

US3222004

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:02:02

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:47:29

US3222004

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:47:29

US3222004

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:48
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:47:29

US3222004
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 16:02:02
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'Jan 2005'	System	30 Oct 2020 17:47:29

US3222004
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 16:02:02
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '2005'	System	30 Oct 2020 17:47:29

US3222004
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 16:02:02
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:47:29

US3222004
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 16:02:02
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	30 Oct 2020 17:47:29

US3222004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:28
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:05

US3222004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:28
User entered '06 Aug 2020'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:05

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:28
User entered '08:58'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:05

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '06 Aug 2020 08:58'	System	06 Aug 2020 15:31:05

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:28
User entered '162.5' cm	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:05
DataPoint set to visible.	System	06 Aug 2020 14:19:12

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:28
User entered '63.2' kg	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:05
DataPoint set to visible.	System	06 Aug 2020 14:19:12

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
Amendment Manager: User entered '23.93373'	System	16 Sep 2020 23:45:03
User entered '23.9'	System	06 Aug 2020 15:31:05
DataPoint set to visible.	System	06 Aug 2020 14:19:12

FDA-CBER-2022-1614-3552965

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'kg/m2'	System	06 Aug 2020 15:31:05
DataPoint set to visible.	System	06 Aug 2020 14:19:12

US3222004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:57
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:52:51
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:02
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:09:30
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:30:29
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:28
User entered '36.9' C	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:05

FDA-CBER-2022-1614-3552967

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:57
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:02
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:02
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:28
User entered 'Oral (Oral)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:05

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:28
User entered empty.	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:05

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:57
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:52:55
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:28
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:02
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:30:35
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:28
User entered '63'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:05

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'bpm'	System	06 Aug 2020 15:31:05

US3222004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:57
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:53:01
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:39
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:02
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:30:44
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:28
User entered '17'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:05

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'breaths/min'	System	06 Aug 2020 15:31:05

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:57
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:53:04
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:53
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:02
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:30:50
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:28
User entered '128'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:05

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'mmHg'	System	06 Aug 2020 15:31:05

US3222004

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:43:57
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:53:07
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:11:07
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 16:10:02
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:30:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:28
User entered '90'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:05

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'mmHg'	System	06 Aug 2020 15:31:05

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18

US3222004
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18

Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 16:02:02
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:34
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:57

US3222004
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 16:02:02

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 15:09:53
Comment added 'SCREENING DATE IS 06AUG2020.'.	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 18:27:48
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 19:39:00
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:34
User entered '06 Aug 2020'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:31:57

US3222004
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:02:02
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:37
User entered '06 Aug 2020'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:33:00

US3222004
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:02:02

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:37
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:33:00

US3222004
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:02:02
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 16:45:57
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'MEDHX updated' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	27 Aug 2020 18:50:14
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:37
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 07:11:57
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	06 Aug 2020 15:33:26
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:33:26
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	06 Aug 2020 15:33:00
User entered empty.	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:33:00

US3222004
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:02:02
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:37
User entered empty.	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:33:00

US3222004

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:02:02

If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:37
User entered empty.	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:33:00

US3222004

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:02:02

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:37
User entered '0'	Crystal Paccione (b) (4)	06 Aug 2020 15:33:00

US3222004

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:37
User entered empty.	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:33:00

US3222004
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 16:02:02
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:37
User entered '1'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:33:00

US3222004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 15:36:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 15:36:15
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:36:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 14:19:51
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:02:02
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 15:36:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 15:36:15
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:36:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 14:19:51
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:02:02
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) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 15:36:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 15:36:15
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:36:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 14:19:51
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:02:02
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) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 15:36:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 15:36:15
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:36:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 14:19:51
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 15:36:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 15:36:15
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:36:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 14:19:51
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 15:36:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 15:36:15
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:36:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 14:19:51
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 15:36:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 15:36:15
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:36:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 14:19:51
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 15:36:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 15:36:15
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:36:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 14:19:51
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:15:45
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 15:36:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 15:36:15
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:36:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 14:19:51
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 15:36:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 15:36:15
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:36:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 14:19:51
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:02:02
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 15:36:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 15:36:15
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:36:15
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 14:19:51
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:02:02
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query ''No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	06 Aug 2020 15:37:03
User entered '0' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:37:03
User opened query ''No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	06 Aug 2020 15:36:15
User entered '1' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:36:15
User entered '0'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:02:02
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User entered '0'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

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US3222004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User entered '0'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User entered '0'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:15:45
User entered '0'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User entered '1'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:02:02
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '0'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 16:02:02
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:45
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:19:51

US3222004
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:15:57
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:20:14

US3222004
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 16:15:36
User entered '06 Aug 2020' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 16:15:36
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:15:57
User entered '6 Aug 2020'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:20:14

US3222004
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:15:57
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:20:14

US3222004
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'VISIT1'	(b) (4), (b) (6) System	06 Aug 2020 14:20:14

US3222004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:16:01
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 13:29:51

US3222004
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:02:02
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:16:01
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:26:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:26:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 13:29:51
User entered '184913' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 13:29:51

US3222004
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:02:02

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:01
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	06 Aug 2020 13:29:51

US3222004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

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)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:01
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:20:46

US3222004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:16:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	07 Aug 2020 22:01:58
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:20:46

US3222004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:01
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:20:46

US3222004
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 16:02:02
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:01
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:20:46

FDA-CBER-2022-1614-3553021

US3222004

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:01
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:20:46

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:02:02
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:29:34
Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly. ' answered by data change (Site from DM).	System	11 Sep 2020 18:18:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 18:18:33
User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:19:56
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:19:12
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 20:37:27
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:30:35
User closed query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:30:35
Query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:16
DataPoint Un-verified.	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:07
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:07
User opened query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:31:41

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:02:02
Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '162.5' cm	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 10:29:35
Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM).	System	11 Sep 2020 18:18:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 18:18:33
User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:20:17
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:19:14
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 20:37:34
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:30:41
User closed query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:30:41
Query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:25
DataPoint Un-verified.	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:07
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:07
User opened query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:31:46
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:16:04

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:02:02
Weight

Audit	User	Time (GMT)
User entered '63.2' kg	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:02:02
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:29:34
Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly. ' answered by data change (Site from DM).	System	11 Sep 2020 18:18:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 18:18:33
User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:19:56
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:19:12
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 20:37:27
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:30:35
User closed query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:30:35
Query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:16
DataPoint Un-verified.	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:07
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:07
User opened query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:31:41

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:02:02
Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '162.5' cm	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:02:02
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 10:29:35
Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM).	System	11 Sep 2020 18:18:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 18:18:33
User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:20:17
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:19:14
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 20:37:34
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:30:41
User closed query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:30:41
Query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:25
DataPoint Un-verified.	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:07
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:07
User opened query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:31:46
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:16:04

US3222004

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:02:02
Weight

Audit	User	Time (GMT)
User entered '63.2' kg	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:02:02
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User accepted default value 'Pre-Dose (PREDOSE)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '06 Aug 2020'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '08:58'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '06 Aug 2020 08:58'	(b) (4), (b) (6) System	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '36.9' C	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered 'Oral (Oral)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:02:02
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered empty.	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '63'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'bpm'	(b) (4), (b) (6) System	06 Aug 2020 15:43:36

FDA-CBER-2022-1614-3553040

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '17'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'breaths/min'	(b) (4), (b) (6) System	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '128'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '90'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 15:43:36

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:02:02
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 10:29:34
Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly. ' answered by data change (Site from DM).	System	11 Sep 2020 18:18:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 18:18:33
User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:19:56
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:19:12
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 20:37:27
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:30:35
User closed query ''Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify''.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:30:35
Query ''Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify''.' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:16
DataPoint Un-verified.	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:07
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:07
User opened query ''Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify''.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:31:41

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:02:02

Height

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '162.5' cm	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:02:02
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 10:29:35
Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM).	System	11 Sep 2020 18:18:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	11 Sep 2020 18:18:33
User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:20:17
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:19:14
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Albert Garcia (b) (4) (b) (4)	04 Sep 2020 20:37:34
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:30:41
User closed query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:30:41
Query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:25
DataPoint Un-verified.	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:07
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 18:28:07
User opened query '"Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:31:46
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:16:04

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 16:02:02
Weight

Audit	User	Time (GMT)
User entered '63.2' kg	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User accepted default value 'Post-Dose (POSTDOSE)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:02:02
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '06 Aug 2020'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:16:04
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 17:58:36
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per pg. 73 of the protocol its a 30 min. post dose easement time' (Site from System).	Crystal Paccione (b) (4)	06 Aug 2020 15:45:21
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	06 Aug 2020 15:43:36
User entered '10:35'	Crystal Paccione (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '06 Aug 2020 10:35'	(b) (4), (b) (6) System	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '36.7' C	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered 'Oral (Oral)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:02:02
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered empty.	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '73'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'bpm'	(b) (4), (b) (6) System	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '16'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'breaths/min'	(b) (4), (b) (6) System	06 Aug 2020 15:43:36

FDA-CBER-2022-1614-3553062

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '126'	Crystal Paccione (b) (4)	06 Aug 2020 15:43:36

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 15:43:36

FDA-CBER-2022-1614-3553064

US3222004

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:04
User entered '94'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:43:36

US3222004
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:02:02
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'mmHg'	(b) (4), (b) (6) System	06 Aug 2020 15:43:36

US3222004

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:07
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:45:59

US3222004
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 16:02:02
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:07
User entered '06 Aug 2020'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:45:59

US3222004
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:02:02
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:10
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:21:14

US3222004
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:02:02
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:10
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:21:14

US3222004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

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)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:10
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:21:14

US3222004
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:02:02
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	06 Aug 2020 14:21:14

US3222004

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:10
User entered '6 Aug 2020'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:21:14

US3222004
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:02:02

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:10
User entered '09:58'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:21:14

US3222004
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:02:02
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '6 Aug 2020 09:58'	(b) (4), (b) (6) System	06 Aug 2020 14:21:14

US3222004
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:02:02
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:10
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:21:14

US3222004
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:02:02
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Aug 2020 15:16:10
User entered 'ONCE'	System	06 Aug 2020 14:21:14

US3222004
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 16:02:02
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	06 Aug 2020 14:21:14

US3222004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:15
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:46:26

US3222004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	27 Aug 2020 15:16:15
User entered '06 Aug 2020'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:46:26

Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:02:02

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:15
User entered '09:15'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:46:26

US3222004

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '06 Aug 2020 09:15'	(b) (4), (b) (6) System	06 Aug 2020 15:46:26

US3222004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:02:02

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:19
User entered '06 Aug 2020'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:46:54

US3222004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:46:54

US3222004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:19
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:46:54

US3222004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:19
User entered '09:18'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:46:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '06 Aug 2020 09:18'	(b) (4), (b) (6) System	06 Aug 2020 15:46:54

US3222004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:46:54

US3222004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:19
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:46:54

US3222004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:19
User entered empty.	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:46:54

US3222004

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered empty.	(b) (4), (b) (6) System	06 Aug 2020 15:46:54

US3222004

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:16:22
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	06 Aug 2020 14:21:24

US3222004
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '1'	(b) (4), (b) (6) System	06 Aug 2020 14:21:24

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:32:52', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '4b8a9179-ddd4-4deb-b0ba-0ac01fb4a22c'	System	06 Aug 2020 14:33:36
User entered 'Yes (Y)'	System	06 Aug 2020 14:33:36

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:33:02', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '4b8a9179-ddd4-4deb-b0ba-0ac01fb4a22c'	System	06 Aug 2020 14:33:36
User entered '98.0'	System	06 Aug 2020 14:33:36

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:33:26', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '4b8a9179-ddd4-4deb-b0ba-0ac01fb4a22c'	System	06 Aug 2020 14:33:36
User entered 'No (N)'	System	06 Aug 2020 14:33:36

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:33:31', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '4b8a9179-ddd4-4deb-b0ba-0ac01fb4a22c'	System	06 Aug 2020 14:33:36
User entered '06 Aug 2020 10:33'	System	06 Aug 2020 14:33:36

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '06 Aug 2020 10:18'	System	06 Aug 2020 14:21:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '06 Aug 2020 12:48'	System	06 Aug 2020 14:21:14

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US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:12:31', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '09b3961b-33d1-4210-9340-08f59d49c566'	System	07 Aug 2020 01:14:00
User entered 'Yes (Y)'	System	07 Aug 2020 01:14:00

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:12:43', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '09b3961b-33d1-4210-9340-08f59d49c566'	System	07 Aug 2020 01:14:00
User entered '97.9'	System	07 Aug 2020 01:14:00

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:13:11', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '09b3961b-33d1-4210-9340-08f59d49c566'	System	07 Aug 2020 01:14:00
User entered 'No (N)'	System	07 Aug 2020 01:14:00

FDA-CBER-2022-1614-3553104

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:13:57', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '09b3961b-33d1-4210-9340-08f59d49c566'	System	07 Aug 2020 01:14:00
User entered '06 Aug 2020 21:13'	System	07 Aug 2020 01:14:00

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '06 Aug 2020 13:43'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 2'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:00:41', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '15da59e5-af46-4040-ba53-eb7ba46a9cb6'	System	08 Aug 2020 01:02:53
User entered 'Yes (Y)'	System	08 Aug 2020 01:02:53

US3222004

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:01:01', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '15da59e5-af46-4040-ba53-eb7ba46a9cb6'	System	08 Aug 2020 01:02:53
User entered '98.5'	System	08 Aug 2020 01:02:53

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:01:10', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '15da59e5-af46-4040-ba53-eb7ba46a9cb6'	System	08 Aug 2020 01:02:53
User entered 'Yes (Y)'	System	08 Aug 2020 01:02:53

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 19:00:57
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'The patient took Ibuprofen for her headache. She has a long history of daily headaches and occasional migraines. She stated it is not from the site injection or Covid-19 symptoms. I will update her history and conmeds.' (Site from System).	douglas winter (b) (4) (b) (4)	23 Aug 2020 19:15:47
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Aug 2020 01:02:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:01:49', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '15da59e5-af46-4040-ba53-eb7ba46a9cb6'	System	08 Aug 2020 01:02:53
User entered '1'	System	08 Aug 2020 01:02:53

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:01:49', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '15da59e5-af46-4040-ba53-eb7ba46a9cb6'	System	08 Aug 2020 01:02:53
User entered '0'	System	08 Aug 2020 01:02:53

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:02:48', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '15da59e5-af46-4040-ba53-eb7ba46a9cb6'	System	08 Aug 2020 01:02:53
User entered '07 Aug 2020 21:02'	System	08 Aug 2020 01:02:53

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 3'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:50:33', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'b1c2967e-a3c4-455f-b914-d0af225ef00a'	System	09 Aug 2020 00:51:01
User entered 'Yes (Y)'	System	09 Aug 2020 00:51:01

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:50:43', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'b1c2967e-a3c4-455f-b914-d0af225ef00a'	System	09 Aug 2020 00:51:01
User entered '98.7'	System	09 Aug 2020 00:51:01

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:50:50', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'b1c2967e-a3c4-455f-b914-d0af225ef00a'	System	09 Aug 2020 00:51:01
User entered 'No (N)'	System	09 Aug 2020 00:51:01

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:50:57', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'b1c2967e-a3c4-455f-b914-d0af225ef00a'	System	09 Aug 2020 00:51:01
User entered '08 Aug 2020 20:50'	System	09 Aug 2020 00:51:01

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 4'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:01:25', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'b5559be7-43f8-48ae-acf4-08d04524ac96'	System	10 Aug 2020 00:01:56
User entered 'Yes (Y)'	System	10 Aug 2020 00:01:56

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:01:35', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'b5559be7-43f8-48ae-acf4-08d04524ac96'	System	10 Aug 2020 00:01:56
User entered '97.7'	System	10 Aug 2020 00:01:56

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:01:39', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'b5559be7-43f8-48ae-acf4-08d04524ac96'	System	10 Aug 2020 00:01:56
User entered 'No (N)'	System	10 Aug 2020 00:01:56

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:01:54', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'b5559be7-43f8-48ae-acf4-08d04524ac96'	System	10 Aug 2020 00:01:56
User entered '09 Aug 2020 20:01'	System	10 Aug 2020 00:01:56

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 5'	System	06 Aug 2020 14:21:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

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US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 6'	System	06 Aug 2020 14:21:14

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US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-11T21:42:53', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '601933bb-d409-4804-9a25-e871bd35b2be'	System	12 Aug 2020 01:43:32
User entered 'Yes (Y)'	System	12 Aug 2020 01:43:32

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-11T21:43:01', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '601933bb-d409-4804-9a25-e871bd35b2be'	System	12 Aug 2020 01:43:32
User entered '98.3'	System	12 Aug 2020 01:43:32

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-11T21:43:20', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '601933bb-d409-4804-9a25-e871bd35b2be'	System	12 Aug 2020 01:43:32
User entered 'No (N)'	System	12 Aug 2020 01:43:32

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-11T21:43:30', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '601933bb-d409-4804-9a25-e871bd35b2be'	System	12 Aug 2020 01:43:32
User entered '11 Aug 2020 21:43'	System	12 Aug 2020 01:43:32

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 7'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

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US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:21:14

FDA-CBER-2022-1614-3553156

US3222004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:31:40', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a3534d8e-c604-4551-98d1-fadd6bb94344'	System	06 Aug 2020 14:32:17
User entered 'None (1)'	System	06 Aug 2020 14:32:17

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:31:51', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a3534d8e-c604-4551-98d1-fadd6bb94344'	System	06 Aug 2020 14:32:17
User entered 'No (N)'	System	06 Aug 2020 14:32:17

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:31:57', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a3534d8e-c604-4551-98d1-fadd6bb94344'	System	06 Aug 2020 14:32:17
User entered 'No (N)'	System	06 Aug 2020 14:32:17

US3222004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:32:03', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a3534d8e-c604-4551-98d1-fadd6bb94344'	System	06 Aug 2020 14:32:17
User entered 'None (1)'	System	06 Aug 2020 14:32:17

US3222004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:32:09', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a3534d8e-c604-4551-98d1-fadd6bb94344'	System	06 Aug 2020 14:32:17
User entered '06 Aug 2020 10:32'	System	06 Aug 2020 14:32:17

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '06 Aug 2020 10:18'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '06 Aug 2020 12:48'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:14:36', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e77d231d-3b47-44ec-866a-ea2120200473'	System	07 Aug 2020 01:15:25
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 01:15:25

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:14:43', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e77d231d-3b47-44ec-866a-ea2120200473'	System	07 Aug 2020 01:15:25
User entered 'No (N)'	System	07 Aug 2020 01:15:25

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:14:55', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e77d231d-3b47-44ec-866a-ea2120200473'	System	07 Aug 2020 01:15:25
User entered 'No (N)'	System	07 Aug 2020 01:15:25

US3222004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:15:05', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e77d231d-3b47-44ec-866a-ea2120200473'	System	07 Aug 2020 01:15:25
User entered 'None (1)'	System	07 Aug 2020 01:15:25

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:15:23', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e77d231d-3b47-44ec-866a-ea2120200473'	System	07 Aug 2020 01:15:25
User entered '06 Aug 2020 21:15'	System	07 Aug 2020 01:15:25

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '06 Aug 2020 13:43'	System	06 Aug 2020 14:21:14

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PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 2'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:03:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e5d9a420-a814-4bf1-a4d4-cb5f82c437f6'	System	08 Aug 2020 01:03:27
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 01:03:27

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:03:04', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e5d9a420-a814-4bf1-a4d4-cb5f82c437f6'	System	08 Aug 2020 01:03:27
User entered 'No (N)'	System	08 Aug 2020 01:03:27

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:03:07', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e5d9a420-a814-4bf1-a4d4-cb5f82c437f6'	System	08 Aug 2020 01:03:27
User entered 'No (N)'	System	08 Aug 2020 01:03:27

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:03:16', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e5d9a420-a814-4bf1-a4d4-cb5f82c437f6'	System	08 Aug 2020 01:03:27
User entered 'None (1)'	System	08 Aug 2020 01:03:27

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:03:25', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e5d9a420-a814-4bf1-a4d4-cb5f82c437f6'	System	08 Aug 2020 01:03:27
User entered '07 Aug 2020 21:03'	System	08 Aug 2020 01:03:27

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 3'	System	06 Aug 2020 14:21:14

US3222004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:51:08', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '79789d36-8104-47a7-970e-b24d87b3d380'	System	09 Aug 2020 00:51:31
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 00:51:31

US3222004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:51:14', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '79789d36-8104-47a7-970e-b24d87b3d380'	System	09 Aug 2020 00:51:31
User entered 'No (N)'	System	09 Aug 2020 00:51:31

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:51:17', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '79789d36-8104-47a7-970e-b24d87b3d380'	System	09 Aug 2020 00:51:31
User entered 'No (N)'	System	09 Aug 2020 00:51:31

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:51:21', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '79789d36-8104-47a7-970e-b24d87b3d380'	System	09 Aug 2020 00:51:31
User entered 'None (1)'	System	09 Aug 2020 00:51:31

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:51:29', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '79789d36-8104-47a7-970e-b24d87b3d380'	System	09 Aug 2020 00:51:31
User entered '08 Aug 2020 20:51'	System	09 Aug 2020 00:51:31

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:02:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

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US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 4'	System	06 Aug 2020 14:21:14

US3222004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'c9275e3c-f495-4f40-b9a1-5b4184321bac'	System	10 Aug 2020 00:02:22
User entered 'None (1)'	System	10 Aug 2020 00:02:22

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:03', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'c9275e3c-f495-4f40-b9a1-5b4184321bac'	System	10 Aug 2020 00:02:22
User entered 'No (N)'	System	10 Aug 2020 00:02:22

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:07', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'c9275e3c-f495-4f40-b9a1-5b4184321bac'	System	10 Aug 2020 00:02:22
User entered 'No (N)'	System	10 Aug 2020 00:02:22

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:10', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'c9275e3c-f495-4f40-b9a1-5b4184321bac'	System	10 Aug 2020 00:02:22
User entered 'None (1)'	System	10 Aug 2020 00:02:22

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:16', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'c9275e3c-f495-4f40-b9a1-5b4184321bac'	System	10 Aug 2020 00:02:22
User entered '09 Aug 2020 20:02'	System	10 Aug 2020 00:02:22

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 5'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 6'	System	06 Aug 2020 14:21:14

US3222004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-11T21:43:37', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '0c3f7a4f-348b-4d3a-b3ac-c8d534e1a895'	System	12 Aug 2020 01:43:57
User entered 'None (1)'	System	12 Aug 2020 01:43:57

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-11T21:43:41', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '0c3f7a4f-348b-4d3a-b3ac-c8d534e1a895'	System	12 Aug 2020 01:43:57
User entered 'No (N)'	System	12 Aug 2020 01:43:57

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-11T21:43:44', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '0c3f7a4f-348b-4d3a-b3ac-c8d534e1a895'	System	12 Aug 2020 01:43:57
User entered 'No (N)'	System	12 Aug 2020 01:43:57

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-11T21:43:50', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '0c3f7a4f-348b-4d3a-b3ac-c8d534e1a895'	System	12 Aug 2020 01:43:57
User entered 'None (1)'	System	12 Aug 2020 01:43:57

US3222004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-11T21:43:55', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '0c3f7a4f-348b-4d3a-b3ac-c8d534e1a895'	System	12 Aug 2020 01:43:57
User entered '11 Aug 2020 21:43'	System	12 Aug 2020 01:43:57

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 7'	System	06 Aug 2020 14:21:14

US3222004

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02
Please record - **REDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:33:41', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '00fafd9b-26dc-4207-a359-db2cb9518926'	System	06 Aug 2020 14:34:16
User entered 'None (0)'	System	06 Aug 2020 14:34:16

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:33:45', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '00fafd9b-26dc-4207-a359-db2cb9518926'	System	06 Aug 2020 14:34:16
User entered 'None (0)'	System	06 Aug 2020 14:34:16

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:33:49', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '00fafd9b-26dc-4207-a359-db2cb9518926'	System	06 Aug 2020 14:34:16
User entered 'None (0)'	System	06 Aug 2020 14:34:16

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:33:56', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '00fafd9b-26dc-4207-a359-db2cb9518926'	System	06 Aug 2020 14:34:16
User entered 'None (0)'	System	06 Aug 2020 14:34:16

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:33:59', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '00fafd9b-26dc-4207-a359-db2cb9518926'	System	06 Aug 2020 14:34:16
User entered 'None (0)'	System	06 Aug 2020 14:34:16

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:34:03', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '00fafd9b-26dc-4207-a359-db2cb9518926'	System	06 Aug 2020 14:34:16
User entered 'None (0)'	System	06 Aug 2020 14:34:16

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:34:07', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '00fafd9b-26dc-4207-a359-db2cb9518926'	System	06 Aug 2020 14:34:16
User entered 'No (N)'	System	06 Aug 2020 14:34:16

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T10:34:11', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '00fafd9b-26dc-4207-a359-db2cb9518926'	System	06 Aug 2020 14:34:16
User entered '06 Aug 2020 10:34'	System	06 Aug 2020 14:34:16

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '06 Aug 2020 10:18'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '06 Aug 2020 12:48'	System	06 Aug 2020 14:21:14

Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:15:35', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a780e36-e49d-4970-9e4c-f770beda15e8'	System	07 Aug 2020 01:16:36
User entered 'None (0)'	System	07 Aug 2020 01:16:36

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:15:40', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a780e36-e49d-4970-9e4c-f770beda15e8'	System	07 Aug 2020 01:16:36
User entered 'None (0)'	System	07 Aug 2020 01:16:36

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:15:47', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a780e36-e49d-4970-9e4c-f770beda15e8'	System	07 Aug 2020 01:16:36
User entered 'None (0)'	System	07 Aug 2020 01:16:36

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:15:56', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a780e36-e49d-4970-9e4c-f770beda15e8'	System	07 Aug 2020 01:16:36
User entered 'None (0)'	System	07 Aug 2020 01:16:36

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:16:01', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a780e36-e49d-4970-9e4c-f770beda15e8'	System	07 Aug 2020 01:16:36
User entered 'None (0)'	System	07 Aug 2020 01:16:36

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:16:07', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a780e36-e49d-4970-9e4c-f770beda15e8'	System	07 Aug 2020 01:16:36
User entered 'None (0)'	System	07 Aug 2020 01:16:36

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:16:25', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a780e36-e49d-4970-9e4c-f770beda15e8'	System	07 Aug 2020 01:16:36
User entered 'No (N)'	System	07 Aug 2020 01:16:36

US3222004

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-06T21:16:33', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a780e36-e49d-4970-9e4c-f770beda15e8'	System	07 Aug 2020 01:16:36
User entered '06 Aug 2020 21:16'	System	07 Aug 2020 01:16:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '06 Aug 2020 13:43'	System	06 Aug 2020 14:21:14

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US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 2'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:03:48', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f6940a87-358f-4872-8b83-6ccb6a3b49e9'	System	08 Aug 2020 01:05:58
User entered 'Any use of prescription pain reliever or prevents daily activity (3)'	System	08 Aug 2020 01:05:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:03:55', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f6940a87-358f-4872-8b83-6ccb6a3b49e9'	System	08 Aug 2020 01:05:58
User entered 'None (0)'	System	08 Aug 2020 01:05:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f6940a87-358f-4872-8b83-6ccb6a3b49e9'	System	08 Aug 2020 01:05:58
User entered 'None (0)'	System	08 Aug 2020 01:05:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:04:04', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f6940a87-358f-4872-8b83-6ccb6a3b49e9'	System	08 Aug 2020 01:05:58
User entered 'None (0)'	System	08 Aug 2020 01:05:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:04:09', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f6940a87-358f-4872-8b83-6ccb6a3b49e9'	System	08 Aug 2020 01:05:58
User entered 'None (0)'	System	08 Aug 2020 01:05:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:04:16', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f6940a87-358f-4872-8b83-6ccb6a3b49e9'	System	08 Aug 2020 01:05:58
User entered 'None (0)'	System	08 Aug 2020 01:05:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:05:45', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f6940a87-358f-4872-8b83-6ccb6a3b49e9'	System	08 Aug 2020 01:05:58
User entered 'No (N)'	System	08 Aug 2020 01:05:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-07T21:05:55', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f6940a87-358f-4872-8b83-6ccb6a3b49e9'	System	08 Aug 2020 01:05:58
User entered '07 Aug 2020 21:05'	System	08 Aug 2020 01:05:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 3'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:51:43', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f459912f-588d-43f9-84f8-b83f586d0a93'	System	09 Aug 2020 00:52:23
User entered 'None (0)'	System	09 Aug 2020 00:52:23

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:51:48', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f459912f-588d-43f9-84f8-b83f586d0a93'	System	09 Aug 2020 00:52:23
User entered 'None (0)'	System	09 Aug 2020 00:52:23

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:51:52', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f459912f-588d-43f9-84f8-b83f586d0a93'	System	09 Aug 2020 00:52:23
User entered 'None (0)'	System	09 Aug 2020 00:52:23

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:51:58', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f459912f-588d-43f9-84f8-b83f586d0a93'	System	09 Aug 2020 00:52:23
User entered 'None (0)'	System	09 Aug 2020 00:52:23

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:52:03', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f459912f-588d-43f9-84f8-b83f586d0a93'	System	09 Aug 2020 00:52:23
User entered 'None (0)'	System	09 Aug 2020 00:52:23

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:52:07', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f459912f-588d-43f9-84f8-b83f586d0a93'	System	09 Aug 2020 00:52:23
User entered 'None (0)'	System	09 Aug 2020 00:52:23

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:52:12', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f459912f-588d-43f9-84f8-b83f586d0a93'	System	09 Aug 2020 00:52:23
User entered 'No (N)'	System	09 Aug 2020 00:52:23

US3222004

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-08T20:52:20', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f459912f-588d-43f9-84f8-b83f586d0a93'	System	09 Aug 2020 00:52:23
User entered '08 Aug 2020 20:52'	System	09 Aug 2020 00:52:23

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 4'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:23', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '32d23366-a77e-48ad-858d-722375ee2aef'	System	10 Aug 2020 00:02:59
User entered 'None (0)'	System	10 Aug 2020 00:02:59

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:28', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '32d23366-a77e-48ad-858d-722375ee2aef'	System	10 Aug 2020 00:02:59
User entered 'None (0)'	System	10 Aug 2020 00:02:59

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:31', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '32d23366-a77e-48ad-858d-722375ee2aef'	System	10 Aug 2020 00:02:59
User entered 'None (0)'	System	10 Aug 2020 00:02:59

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:35', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '32d23366-a77e-48ad-858d-722375ee2aef'	System	10 Aug 2020 00:02:59
User entered 'None (0)'	System	10 Aug 2020 00:02:59

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:40', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '32d23366-a77e-48ad-858d-722375ee2aef'	System	10 Aug 2020 00:02:59
User entered 'None (0)'	System	10 Aug 2020 00:02:59

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:43', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '32d23366-a77e-48ad-858d-722375ee2aef'	System	10 Aug 2020 00:02:59
User entered 'None (0)'	System	10 Aug 2020 00:02:59

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:48', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '32d23366-a77e-48ad-858d-722375ee2aef'	System	10 Aug 2020 00:02:59
User entered 'No (N)'	System	10 Aug 2020 00:02:59

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-08-09T20:02:56', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '32d23366-a77e-48ad-858d-722375ee2aef'	System	10 Aug 2020 00:02:59
User entered '09 Aug 2020 20:02'	System	10 Aug 2020 00:02:59

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 5'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 6'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

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US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 7'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 14:21:14

US3222004
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 14:21:14

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 09:20:21
User entered 'Yes (Y)'	Thais Truffa (b) (4)	13 Aug 2020 19:01:21

US3222004

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 09:20:21
User entered '13 Aug 2020'	Thais Truffa (b) (4)	13 Aug 2020 19:01:21

US3222004
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 09:20:21
User entered 'Contact Made (CONTACT MADE)'	Thais Truffa (b) (4)	13 Aug 2020 19:01:21

US3222004
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 09:20:21
User entered empty.	Thais Truffa (b) (4)	13 Aug 2020 19:01:21

US3222004
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 09:20:28
User entered 'Yes (Y)'	Thais Truffa (b) (4)	13 Aug 2020 19:01:26

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US3222004
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '1'	(b) (4), (b) (6) System	13 Aug 2020 19:01:26

US3222004
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 09:20:37
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:20:49

US3222004

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 09:20:37
User entered '20 Aug 2020'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:20:49

US3222004
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 09:20:37
User entered 'Contact Made (CONTACT MADE)'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:20:49

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US3222004
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 09:20:37
User entered 'NO AE'S OR CHANGES NOTED OR EXPRESSED. DENIES COVID-19 SYMPTOMS. NO CONMED CHANGES OR VACCINES.'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:20:49

US3222004

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 09:20:41
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	24 Aug 2020 11:48:52

US3222004
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '1'	(b) (4), (b) (6) System	24 Aug 2020 11:48:52

US3222004
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:17
User entered 'Yes (Y)'	Thais Truffa (b) (4)	10 Sep 2020 19:36:01

US3222004
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:17
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Sep 2020 19:37:34
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	10 Sep 2020 19:37:34
User entered '27 Aug 2020' reason for change: Data Entry Error	Thais Truffa (b) (4)	10 Sep 2020 19:37:34
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Sep 2020 19:36:01
User entered '01 Sep 2020'	Thais Truffa (b) (4)	10 Sep 2020 19:36:01

US3222004
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:17
User entered 'Contact Made (CONTACT MADE)'	Thais Truffa (b) (4)	10 Sep 2020 19:36:01

US3222004
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:17
User entered empty.	Thais Truffa (b) (4)	10 Sep 2020 19:36:01

US3222004
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:29:22
User entered 'Yes (Y)'	Thais Truffa (b) (4)	10 Sep 2020 19:38:45

US3222004
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
	(b) (4), (b) (6)	
User entered '1'	System	10 Sep 2020 19:38:45

US3222004
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:52
User entered 'Yes (Y)'	Thais Truffa (b) (4)	10 Sep 2020 19:39:00

US3222004
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:52
User entered '10 Sep 2020'	Thais Truffa (b) (4)	10 Sep 2020 19:39:00

US3222004

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:27:52
User entered 'Home (Home)'	Thais Truffa (b) (4)	10 Sep 2020 19:39:00

US3222004
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'VISIT2'	(b) (4), (b) (6) System	10 Sep 2020 19:39:00

US3222004
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:02:02
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '10 Sep 2020'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '14:38'	Albert Garcia (b) (4)	11 Sep 2020 17:23:15
	(b) (4)	

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '10 Sep 2020 14:38'	(b) (4), (b) (6) System	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '36.7' C	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered 'Oral (Oral)'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:02:02
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered empty.	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '83'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:02:02
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'bpm'	(b) (4), (b) (6) System	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '18'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Sep 2020 17:23:15

US3222004
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 16:02:02
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '129'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '90'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 17:23:15

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US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '10 Sep 2020'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '15:56'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '10 Sep 2020 15:56'	(b) (4), (b) (6) System	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '36.9' C	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered 'Oral (Oral)'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 16:02:02
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered empty.	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '84'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'bpm'	(b) (4), (b) (6) System	11 Sep 2020 17:23:15

FDA-CBER-2022-1614-3553359

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '17'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Sep 2020 17:23:15

FDA-CBER-2022-1614-3553361

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '148'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 17:23:15

FDA-CBER-2022-1614-3553363

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:27:59
User entered '86'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 17:23:15

US3222004

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:06
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:26

FDA-CBER-2022-1614-3553366

US3222004

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:06
User entered '10 Sep 2020'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:26

US3222004
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:02:02
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:12
User entered 'Yes (Y)'	Thais Truffa (b) (4)	10 Sep 2020 19:40:03

US3222004
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:02:02
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:12
User entered empty.	Thais Truffa (b) (4)	10 Sep 2020 19:40:03

US3222004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

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)	04 Apr 2021 17:37:19
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:28:12
User entered empty.	Thais Truffa (b) (4)	10 Sep 2020 19:40:03

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	10 Sep 2020 19:40:03

FDA-CBER-2022-1614-3553371

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:12
User entered '10 Sep 2020'	Thais Truffa (b) (4)	10 Sep 2020 19:40:03

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:02:02

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:12
User entered '15:25'	Thais Truffa (b) (4)	10 Sep 2020 19:40:03

US3222004

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '10 Sep 2020 15:25'	(b) (4), (b) (6) System	10 Sep 2020 19:40:03

US3222004
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:02:02

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:12
User entered 'Left Arm (LEFT ARM)'	Thais Truffa (b) (4)	10 Sep 2020 19:40:03

US3222004
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 16:02:02
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:28:12
User entered 'ONCE'	System	10 Sep 2020 19:40:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	10 Sep 2020 19:40:03

FDA-CBER-2022-1614-3553377

US3222004
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:02:02
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:19
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:48

US3222004

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:19
User entered '10 Sep 2020'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:48

Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 16:02:02
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:19
User entered '14:51'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:23:48

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '10 Sep 2020 14:51'	(b) (4), (b) (6) System	11 Sep 2020 17:23:48

FDA-CBER-2022-1614-3553381

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 16:02:02
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:28:27
User entered '10 Sep 2020'	Albert Garcia (b) (4)	11 Sep 2020 17:24:11
	(b) (4)	

US3222004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:24:11

US3222004
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:02:02
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:27
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:24:11

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:27
User entered '14:58'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:24:11

FDA-CBER-2022-1614-3553385

US3222004
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 16:02:02
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '10 Sep 2020 14:58'	(b) (4), (b) (6) System	11 Sep 2020 17:24:11

US3222004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:24:11

US3222004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:27
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:24:11

US3222004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:28:27
User entered empty.	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:24:11

US3222004

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered empty.	(b) (4), (b) (6) System	11 Sep 2020 17:24:11

US3222004
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:28:35
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	11 Sep 2020 17:24:17

US3222004
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '1'	(b) (4), (b) (6) System	11 Sep 2020 17:24:17

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-10T15:59:23', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6e08a305-00e2-4c5d-ab86-6e0ce3ca2428'	System	10 Sep 2020 20:00:11
User entered 'Yes (Y)'	System	10 Sep 2020 20:00:11

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-10T15:59:42', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6e08a305-00e2-4c5d-ab86-6e0ce3ca2428'	System	10 Sep 2020 20:00:11
User entered '98.5'	System	10 Sep 2020 20:00:11

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-10T15:59:57', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6e08a305-00e2-4c5d-ab86-6e0ce3ca2428'	System	10 Sep 2020 20:00:11
User entered 'No (N)'	System	10 Sep 2020 20:00:11

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-10T16:00:06', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6e08a305-00e2-4c5d-ab86-6e0ce3ca2428'	System	10 Sep 2020 20:00:11
User entered '10 Sep 2020 16:00'	System	10 Sep 2020 20:00:11

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Sep 2020 15:45'	System	10 Sep 2020 19:40:03

Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Sep 2020 18:15'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:40:03

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US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:49:36', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'bd0ca162-f4b5-49c2-97d7-42be91ba0c4f'	System	11 Sep 2020 08:50:10
User entered 'Yes (Y)'	System	11 Sep 2020 08:50:10

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:49:45', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'bd0ca162-f4b5-49c2-97d7-42be91ba0c4f'	System	11 Sep 2020 08:50:10
User entered '96.8'	System	11 Sep 2020 08:50:10

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:49:59', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'bd0ca162-f4b5-49c2-97d7-42be91ba0c4f'	System	11 Sep 2020 08:50:10
User entered 'No (N)'	System	11 Sep 2020 08:50:10

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:50:07', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'bd0ca162-f4b5-49c2-97d7-42be91ba0c4f'	System	11 Sep 2020 08:50:10
User entered '11 Sep 2020 04:50'	System	11 Sep 2020 08:50:10

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Sep 2020 19:10'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 2'	System	10 Sep 2020 19:40:03

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US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T21:59:37', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '333bdd3c-4c1a-4f21-b353-df1011e7d665'	System	12 Sep 2020 02:00:23
User entered 'Yes (Y)'	System	12 Sep 2020 02:00:23

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:00:03', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '333bdd3c-4c1a-4f21-b353-df1011e7d665'	System	12 Sep 2020 02:00:23
User entered '100.4'	System	12 Sep 2020 02:00:23

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:00:11', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '333bdd3c-4c1a-4f21-b353-df1011e7d665'	System	12 Sep 2020 02:00:23
User entered 'No (N)'	System	12 Sep 2020 02:00:23

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:00:18', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '333bdd3c-4c1a-4f21-b353-df1011e7d665'	System	12 Sep 2020 02:00:23
User entered '11 Sep 2020 22:00'	System	12 Sep 2020 02:00:23

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 3'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:48:30', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f8a5b15e-39d4-4bb6-8889-7d0b009002fa'	System	13 Sep 2020 01:48:53
User entered 'Yes (Y)'	System	13 Sep 2020 01:48:53

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:48:36', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f8a5b15e-39d4-4bb6-8889-7d0b009002fa'	System	13 Sep 2020 01:48:53
User entered '98.8'	System	13 Sep 2020 01:48:53

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:48:43', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f8a5b15e-39d4-4bb6-8889-7d0b009002fa'	System	13 Sep 2020 01:48:53
User entered 'No (N)'	System	13 Sep 2020 01:48:53

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:48:49', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f8a5b15e-39d4-4bb6-8889-7d0b009002fa'	System	13 Sep 2020 01:48:53
User entered '12 Sep 2020 21:48'	System	13 Sep 2020 01:48:53

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 4'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:27:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'dfa3c0ed-53ff-4fc4-834f-28d38b476d3d'	System	14 Sep 2020 01:27:22
User entered 'Yes (Y)'	System	14 Sep 2020 01:27:22

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:27:07', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'dfa3c0ed-53ff-4fc4-834f-28d38b476d3d'	System	14 Sep 2020 01:27:22
User entered '98.2'	System	14 Sep 2020 01:27:22

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:27:11', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'dfa3c0ed-53ff-4fc4-834f-28d38b476d3d'	System	14 Sep 2020 01:27:22
User entered 'No (N)'	System	14 Sep 2020 01:27:22

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:27:15', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'dfa3c0ed-53ff-4fc4-834f-28d38b476d3d'	System	14 Sep 2020 01:27:22
User entered '13 Sep 2020 21:27'	System	14 Sep 2020 01:27:22

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 5'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:10:51', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'eb90047b-2033-4dc3-9266-c357cce9ff9f'	System	15 Sep 2020 02:12:06
User entered 'Yes (Y)'	System	15 Sep 2020 02:12:06

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:11:03', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'eb90047b-2033-4dc3-9266-c357cce9ff9f'	System	15 Sep 2020 02:12:06
User entered '98.2'	System	15 Sep 2020 02:12:06

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US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:11:25', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'eb90047b-2033-4dc3-9266-c357cce9ff9f'	System	15 Sep 2020 02:12:06
User entered 'No (N)'	System	15 Sep 2020 02:12:06

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:04', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'eb90047b-2033-4dc3-9266-c357cce9ff9f'	System	15 Sep 2020 02:12:06
User entered '14 Sep 2020 22:12'	System	15 Sep 2020 02:12:06

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 6'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:53:32', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f4a7ea9c-0608-4c4c-b6e2-0f691f1f60d4'	System	16 Sep 2020 01:54:01
User entered 'Yes (Y)'	System	16 Sep 2020 01:54:01

US3222004

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:53:50', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f4a7ea9c-0608-4c4c-b6e2-0f691f1f60d4'	System	16 Sep 2020 01:54:01
User entered '97.7'	System	16 Sep 2020 01:54:01

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:53:54', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f4a7ea9c-0608-4c4c-b6e2-0f691f1f60d4'	System	16 Sep 2020 01:54:01
User entered 'No (N)'	System	16 Sep 2020 01:54:01

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:53:58', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'f4a7ea9c-0608-4c4c-b6e2-0f691f1f60d4'	System	16 Sep 2020 01:54:01
User entered '15 Sep 2020 21:53'	System	16 Sep 2020 01:54:01

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

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US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 7'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:37:54', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e98690b1-f47e-40dd-ba11-636d5c8c1152'	System	17 Sep 2020 02:38:33
User entered 'Yes (Y)'	System	17 Sep 2020 02:38:33

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:38:12', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e98690b1-f47e-40dd-ba11-636d5c8c1152'	System	17 Sep 2020 02:38:33
User entered '97.9'	System	17 Sep 2020 02:38:33

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:38:19', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e98690b1-f47e-40dd-ba11-636d5c8c1152'	System	17 Sep 2020 02:38:33
User entered 'No (N)'	System	17 Sep 2020 02:38:33

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:38:27', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e98690b1-f47e-40dd-ba11-636d5c8c1152'	System	17 Sep 2020 02:38:33
User entered '16 Sep 2020 22:38'	System	17 Sep 2020 02:38:33

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:40:03

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US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-10T16:01:10', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '99c19451-d9b1-4563-a040-4316e1747c05'	System	10 Sep 2020 20:01:20
User entered 'None (1)'	System	10 Sep 2020 20:01:20

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-10T16:01:03', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '99c19451-d9b1-4563-a040-4316e1747c05'	System	10 Sep 2020 20:01:20
User entered 'No (N)'	System	10 Sep 2020 20:01:20

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-10T16:00:36', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '99c19451-d9b1-4563-a040-4316e1747c05'	System	10 Sep 2020 20:01:20
User entered 'No (N)'	System	10 Sep 2020 20:01:20

US3222004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-10T16:00:41', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '99c19451-d9b1-4563-a040-4316e1747c05'	System	10 Sep 2020 20:01:20
User entered 'None (1)'	System	10 Sep 2020 20:01:20

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-10T16:01:17', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '99c19451-d9b1-4563-a040-4316e1747c05'	System	10 Sep 2020 20:01:20
User entered '10 Sep 2020 16:01'	System	10 Sep 2020 20:01:20

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Sep 2020 15:45'	System	10 Sep 2020 19:40:03

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US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Sep 2020 18:15'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:40:03

US3222004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:50:31', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7efcbd10-2f30-4e29-b4c8-5c7a44a7daf5'	System	11 Sep 2020 08:51:29
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 08:51:29

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:50:37', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7efcbd10-2f30-4e29-b4c8-5c7a44a7daf5'	System	11 Sep 2020 08:51:29
User entered 'No (N)'	System	11 Sep 2020 08:51:29

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US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:50:55', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7efcbd10-2f30-4e29-b4c8-5c7a44a7daf5'	System	11 Sep 2020 08:51:29
User entered 'No (N)'	System	11 Sep 2020 08:51:29

US3222004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:51:09', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7efcbd10-2f30-4e29-b4c8-5c7a44a7daf5'	System	11 Sep 2020 08:51:29
User entered 'None (1)'	System	11 Sep 2020 08:51:29

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:51:24', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7efcbd10-2f30-4e29-b4c8-5c7a44a7daf5'	System	11 Sep 2020 08:51:29
User entered '11 Sep 2020 04:51'	System	11 Sep 2020 08:51:29

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Sep 2020 19:10'	System	10 Sep 2020 19:40:03

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US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 2'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:00:28', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'bf76b557-c10c-4840-912f-02567e2eba81'	System	12 Sep 2020 02:00:55
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 02:00:55

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:00:32', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'bf76b557-c10c-4840-912f-02567e2eba81'	System	12 Sep 2020 02:00:55
User entered 'No (N)'	System	12 Sep 2020 02:00:55

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US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:00:36', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'bf76b557-c10c-4840-912f-02567e2eba81'	System	12 Sep 2020 02:00:55
User entered 'No (N)'	System	12 Sep 2020 02:00:55

US3222004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:00:45', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'bf76b557-c10c-4840-912f-02567e2eba81'	System	12 Sep 2020 02:00:55
User entered 'None (1)'	System	12 Sep 2020 02:00:55

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:00:52', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'bf76b557-c10c-4840-912f-02567e2eba81'	System	12 Sep 2020 02:00:55
User entered '11 Sep 2020 22:00'	System	12 Sep 2020 02:00:55

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 3'	System	10 Sep 2020 19:40:03

US3222004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:48:57', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '38155049-8c3a-4879-95d2-4f30dd886bc2'	System	13 Sep 2020 01:49:13
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 01:49:13

FDA-CBER-2022-1614-3553474

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:49:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '38155049-8c3a-4879-95d2-4f30dd886bc2'	System	13 Sep 2020 01:49:13
User entered 'No (N)'	System	13 Sep 2020 01:49:13

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:49:02', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '38155049-8c3a-4879-95d2-4f30dd886bc2'	System	13 Sep 2020 01:49:13
User entered 'No (N)'	System	13 Sep 2020 01:49:13

US3222004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:49:05', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '38155049-8c3a-4879-95d2-4f30dd886bc2'	System	13 Sep 2020 01:49:13
User entered 'None (1)'	System	13 Sep 2020 01:49:13

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:49:11', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '38155049-8c3a-4879-95d2-4f30dd886bc2'	System	13 Sep 2020 01:49:13
User entered '12 Sep 2020 21:49'	System	13 Sep 2020 01:49:13

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 4'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:27:23', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '4ac645fb-0587-4c96-8a5e-8fe1429685c4'	System	14 Sep 2020 01:27:44
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 01:27:44

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:27:27', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '4ac645fb-0587-4c96-8a5e-8fe1429685c4'	System	14 Sep 2020 01:27:44
User entered 'No (N)'	System	14 Sep 2020 01:27:44

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:27:31', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '4ac645fb-0587-4c96-8a5e-8fe1429685c4'	System	14 Sep 2020 01:27:44
User entered 'No (N)'	System	14 Sep 2020 01:27:44

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:27:36', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '4ac645fb-0587-4c96-8a5e-8fe1429685c4'	System	14 Sep 2020 01:27:44
User entered 'None (1)'	System	14 Sep 2020 01:27:44

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:27:40', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '4ac645fb-0587-4c96-8a5e-8fe1429685c4'	System	14 Sep 2020 01:27:44
User entered '13 Sep 2020 21:27'	System	14 Sep 2020 01:27:44

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6))	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 5'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:13', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'dd980255-9f33-4e26-a36d-0b0f13ac2c70'	System	15 Sep 2020 02:12:36
User entered 'None (1)'	System	15 Sep 2020 02:12:36

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:16', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'dd980255-9f33-4e26-a36d-0b0f13ac2c70'	System	15 Sep 2020 02:12:36
User entered 'No (N)'	System	15 Sep 2020 02:12:36

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:19', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'dd980255-9f33-4e26-a36d-0b0f13ac2c70'	System	15 Sep 2020 02:12:36
User entered 'No (N)'	System	15 Sep 2020 02:12:36

US3222004

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:25', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'dd980255-9f33-4e26-a36d-0b0f13ac2c70'	System	15 Sep 2020 02:12:36
User entered 'None (1)'	System	15 Sep 2020 02:12:36

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:32', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'dd980255-9f33-4e26-a36d-0b0f13ac2c70'	System	15 Sep 2020 02:12:36
User entered '14 Sep 2020 22:12'	System	15 Sep 2020 02:12:36

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US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 6'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:04', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '33a53b95-438d-4c45-82a0-6f41c34c78e3'	System	16 Sep 2020 01:54:25
User entered 'None (1)'	System	16 Sep 2020 01:54:25

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:08', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '33a53b95-438d-4c45-82a0-6f41c34c78e3'	System	16 Sep 2020 01:54:25
User entered 'No (N)'	System	16 Sep 2020 01:54:25

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:12', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '33a53b95-438d-4c45-82a0-6f41c34c78e3'	System	16 Sep 2020 01:54:25
User entered 'No (N)'	System	16 Sep 2020 01:54:25

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:15', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '33a53b95-438d-4c45-82a0-6f41c34c78e3'	System	16 Sep 2020 01:54:25
User entered 'None (1)'	System	16 Sep 2020 01:54:25

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:20', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '33a53b95-438d-4c45-82a0-6f41c34c78e3'	System	16 Sep 2020 01:54:25
User entered '15 Sep 2020 21:54'	System	16 Sep 2020 01:54:25

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 7'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:38:50', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'fe55955e-95d2-4449-a66f-f30e1804bc12'	System	17 Sep 2020 02:39:57
User entered 'None (1)'	System	17 Sep 2020 02:39:57

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:38:55', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'fe55955e-95d2-4449-a66f-f30e1804bc12'	System	17 Sep 2020 02:39:57
User entered 'No (N)'	System	17 Sep 2020 02:39:57

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:39:21', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'fe55955e-95d2-4449-a66f-f30e1804bc12'	System	17 Sep 2020 02:39:57
User entered 'No (N)'	System	17 Sep 2020 02:39:57

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:39:30', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'fe55955e-95d2-4449-a66f-f30e1804bc12'	System	17 Sep 2020 02:39:57
User entered 'None (1)'	System	17 Sep 2020 02:39:57

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:39:55', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'fe55955e-95d2-4449-a66f-f30e1804bc12'	System	17 Sep 2020 02:39:57
User entered '16 Sep 2020 22:39'	System	17 Sep 2020 02:39:57

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 16:02:02
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Sep 2020 15:45'	System	10 Sep 2020 19:40:03

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Sep 2020 18:15'	System	10 Sep 2020 19:40:03

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US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:54:11', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a323fe38-0f6d-457d-a806-dadee89d6f9a'	System	11 Sep 2020 08:55:37
User entered 'None (0)'	System	11 Sep 2020 08:55:37

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:55:20', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a323fe38-0f6d-457d-a806-dadee89d6f9a'	System	11 Sep 2020 08:55:37
User entered 'None (0)'	System	11 Sep 2020 08:55:37

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:54:21', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a323fe38-0f6d-457d-a806-dadee89d6f9a'	System	11 Sep 2020 08:55:37
User entered 'None (0)'	System	11 Sep 2020 08:55:37

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:54:26', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a323fe38-0f6d-457d-a806-dadee89d6f9a'	System	11 Sep 2020 08:55:37
User entered 'None (0)'	System	11 Sep 2020 08:55:37

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:54:36', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a323fe38-0f6d-457d-a806-dadee89d6f9a'	System	11 Sep 2020 08:55:37
User entered 'None (0)'	System	11 Sep 2020 08:55:37

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:54:41', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a323fe38-0f6d-457d-a806-dadee89d6f9a'	System	11 Sep 2020 08:55:37
User entered 'None (0)'	System	11 Sep 2020 08:55:37

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:55:09', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a323fe38-0f6d-457d-a806-dadee89d6f9a'	System	11 Sep 2020 08:55:37
User entered 'No (N)'	System	11 Sep 2020 08:55:37

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 16:02:02
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T04:55:32', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a323fe38-0f6d-457d-a806-dadee89d6f9a'	System	11 Sep 2020 08:55:37
User entered '11 Sep 2020 04:55'	System	11 Sep 2020 08:55:37

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '10 Sep 2020 19:10'	System	10 Sep 2020 19:40:03

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PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

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US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 2'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:01:02', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd5fb52f2-7332-4390-bf7e-64b845bec567'	System	12 Sep 2020 02:01:49
User entered 'None (0)'	System	12 Sep 2020 02:01:49

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:01:11', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd5fb52f2-7332-4390-bf7e-64b845bec567'	System	12 Sep 2020 02:01:49
User entered 'None (0)'	System	12 Sep 2020 02:01:49

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:01:15', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd5fb52f2-7332-4390-bf7e-64b845bec567'	System	12 Sep 2020 02:01:49
User entered 'None (0)'	System	12 Sep 2020 02:01:49

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:01:19', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd5fb52f2-7332-4390-bf7e-64b845bec567'	System	12 Sep 2020 02:01:49
User entered 'None (0)'	System	12 Sep 2020 02:01:49

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:01:23', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd5fb52f2-7332-4390-bf7e-64b845bec567'	System	12 Sep 2020 02:01:49
User entered 'None (0)'	System	12 Sep 2020 02:01:49

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:01:29', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd5fb52f2-7332-4390-bf7e-64b845bec567'	System	12 Sep 2020 02:01:49
User entered 'None (0)'	System	12 Sep 2020 02:01:49

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:01:33', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd5fb52f2-7332-4390-bf7e-64b845bec567'	System	12 Sep 2020 02:01:49
User entered 'No (N)'	System	12 Sep 2020 02:01:49

US3222004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-11T22:01:41', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd5fb52f2-7332-4390-bf7e-64b845bec567'	System	12 Sep 2020 02:01:49
User entered '11 Sep 2020 22:01'	System	12 Sep 2020 02:01:49

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 16:02:02

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 3'	System	10 Sep 2020 19:40:03

'(

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:49:18', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6742bf1a-a992-4397-894d-ad4a313ce08e'	System	13 Sep 2020 01:50:07
User entered 'None (0)'	System	13 Sep 2020 01:50:07

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:49:24', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6742bf1a-a992-4397-894d-ad4a313ce08e'	System	13 Sep 2020 01:50:07
User entered 'None (0)'	System	13 Sep 2020 01:50:07

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:49:27', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6742bf1a-a992-4397-894d-ad4a313ce08e'	System	13 Sep 2020 01:50:07
User entered 'None (0)'	System	13 Sep 2020 01:50:07

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:49:33', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6742bf1a-a992-4397-894d-ad4a313ce08e'	System	13 Sep 2020 01:50:07
User entered 'None (0)'	System	13 Sep 2020 01:50:07

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:49:37', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6742bf1a-a992-4397-894d-ad4a313ce08e'	System	13 Sep 2020 01:50:07
User entered 'None (0)'	System	13 Sep 2020 01:50:07

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:49:44', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6742bf1a-a992-4397-894d-ad4a313ce08e'	System	13 Sep 2020 01:50:07
User entered 'None (0)'	System	13 Sep 2020 01:50:07

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:50:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6742bf1a-a992-4397-894d-ad4a313ce08e'	System	13 Sep 2020 01:50:07
User entered 'No (N)'	System	13 Sep 2020 01:50:07

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-12T21:50:04', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6742bf1a-a992-4397-894d-ad4a313ce08e'	System	13 Sep 2020 01:50:07
User entered '12 Sep 2020 21:50'	System	13 Sep 2020 01:50:07

Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 4'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:27:48', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd9ff22da-18ff-45fa-9acf-a393e683998b'	System	14 Sep 2020 01:28:29
User entered 'None (0)'	System	14 Sep 2020 01:28:29

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:27:56', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd9ff22da-18ff-45fa-9acf-a393e683998b'	System	14 Sep 2020 01:28:29
User entered 'None (0)'	System	14 Sep 2020 01:28:29

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:28:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd9ff22da-18ff-45fa-9acf-a393e683998b'	System	14 Sep 2020 01:28:29
User entered 'None (0)'	System	14 Sep 2020 01:28:29

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:28:03', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd9ff22da-18ff-45fa-9acf-a393e683998b'	System	14 Sep 2020 01:28:29
User entered 'None (0)'	System	14 Sep 2020 01:28:29

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:28:07', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd9ff22da-18ff-45fa-9acf-a393e683998b'	System	14 Sep 2020 01:28:29
User entered 'None (0)'	System	14 Sep 2020 01:28:29

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:28:11', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd9ff22da-18ff-45fa-9acf-a393e683998b'	System	14 Sep 2020 01:28:29
User entered 'None (0)'	System	14 Sep 2020 01:28:29

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:28:15', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd9ff22da-18ff-45fa-9acf-a393e683998b'	System	14 Sep 2020 01:28:29
User entered 'No (N)'	System	14 Sep 2020 01:28:29

US3222004

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-13T21:28:26', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'd9ff22da-18ff-45fa-9acf-a393e683998b'	System	14 Sep 2020 01:28:29
User entered '13 Sep 2020 21:28'	System	14 Sep 2020 01:28:29

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

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US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 5'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:39', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a5e1b354-2c58-4ffc-84cd-088e7caa4828'	System	15 Sep 2020 02:13:18
User entered 'None (0)'	System	15 Sep 2020 02:13:18

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:42', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a5e1b354-2c58-4ffc-84cd-088e7caa4828'	System	15 Sep 2020 02:13:18
User entered 'None (0)'	System	15 Sep 2020 02:13:18

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:45', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a5e1b354-2c58-4ffc-84cd-088e7caa4828'	System	15 Sep 2020 02:13:18
User entered 'None (0)'	System	15 Sep 2020 02:13:18

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:49', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a5e1b354-2c58-4ffc-84cd-088e7caa4828'	System	15 Sep 2020 02:13:18
User entered 'None (0)'	System	15 Sep 2020 02:13:18

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:52', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a5e1b354-2c58-4ffc-84cd-088e7caa4828'	System	15 Sep 2020 02:13:18
User entered 'None (0)'	System	15 Sep 2020 02:13:18

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:55', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a5e1b354-2c58-4ffc-84cd-088e7caa4828'	System	15 Sep 2020 02:13:18
User entered 'None (0)'	System	15 Sep 2020 02:13:18

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:12:57', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a5e1b354-2c58-4ffc-84cd-088e7caa4828'	System	15 Sep 2020 02:13:18
User entered 'No (N)'	System	15 Sep 2020 02:13:18

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-14T22:13:15', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a5e1b354-2c58-4ffc-84cd-088e7caa4828'	System	15 Sep 2020 02:13:18
User entered '14 Sep 2020 22:13'	System	15 Sep 2020 02:13:18

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

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US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 6'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:26', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '48016b54-82cd-4366-a737-caebc2853de4'	System	16 Sep 2020 01:54:59
User entered 'None (0)'	System	16 Sep 2020 01:54:59

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:28', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '48016b54-82cd-4366-a737-caebc2853de4'	System	16 Sep 2020 01:54:59
User entered 'None (0)'	System	16 Sep 2020 01:54:59

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:31', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '48016b54-82cd-4366-a737-caebc2853de4'	System	16 Sep 2020 01:54:59
User entered 'None (0)'	System	16 Sep 2020 01:54:59

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:35', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '48016b54-82cd-4366-a737-caebc2853de4'	System	16 Sep 2020 01:54:59
User entered 'None (0)'	System	16 Sep 2020 01:54:59

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:38', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '48016b54-82cd-4366-a737-caebc2853de4'	System	16 Sep 2020 01:54:59
User entered 'None (0)'	System	16 Sep 2020 01:54:59

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:41', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '48016b54-82cd-4366-a737-caebc2853de4'	System	16 Sep 2020 01:54:59
User entered 'None (0)'	System	16 Sep 2020 01:54:59

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:45', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '48016b54-82cd-4366-a737-caebc2853de4'	System	16 Sep 2020 01:54:59
User entered 'No (N)'	System	16 Sep 2020 01:54:59

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-15T21:54:54', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '48016b54-82cd-4366-a737-caebc2853de4'	System	16 Sep 2020 01:54:59
User entered '15 Sep 2020 21:54'	System	16 Sep 2020 01:54:59

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 16:02:02
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	10 Sep 2020 19:40:03
User entered 'Day 7'	System	10 Sep 2020 19:40:03

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:40:02', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a0267dc-f96d-46b6-bed2-7b7bab009bab'	System	17 Sep 2020 02:41:12
User entered 'None (0)'	System	17 Sep 2020 02:41:12

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:40:08', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a0267dc-f96d-46b6-bed2-7b7bab009bab'	System	17 Sep 2020 02:41:12
User entered 'None (0)'	System	17 Sep 2020 02:41:12

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:40:11', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a0267dc-f96d-46b6-bed2-7b7bab009bab'	System	17 Sep 2020 02:41:12
User entered 'None (0)'	System	17 Sep 2020 02:41:12

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:40:14', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a0267dc-f96d-46b6-bed2-7b7bab009bab'	System	17 Sep 2020 02:41:12
User entered 'None (0)'	System	17 Sep 2020 02:41:12

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:40:17', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a0267dc-f96d-46b6-bed2-7b7bab009bab'	System	17 Sep 2020 02:41:12
User entered 'None (0)'	System	17 Sep 2020 02:41:12

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:40:20', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a0267dc-f96d-46b6-bed2-7b7bab009bab'	System	17 Sep 2020 02:41:12
User entered 'None (0)'	System	17 Sep 2020 02:41:12

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:40:59', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a0267dc-f96d-46b6-bed2-7b7bab009bab'	System	17 Sep 2020 02:41:12
User entered 'No (N)'	System	17 Sep 2020 02:41:12

US3222004
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 16:02:02
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (314cc7cd4516af47)', Time: '2020-09-16T22:41:06', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6a0267dc-f96d-46b6-bed2-7b7bab009bab'	System	17 Sep 2020 02:41:12
User entered '16 Sep 2020 22:41'	System	17 Sep 2020 02:41:12

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PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:40:03

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:40:03

FDA-CBER-2022-1614-3553600

US3222004
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:29:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '17 Sep 2020'	Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:29:33

FDA-CBER-2022-1614-3553602

US3222004
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:29:33

US3222004
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:29:33

US3222004

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 20:29:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 20:29:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	12 Oct 2020 20:29:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 13:15:50
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	09 Oct 2020 13:15:50
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	09 Oct 2020 13:15:40

US3222004
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '1'	System	12 Oct 2020 20:29:04
User entered empty.	System	09 Oct 2020 13:15:50
User entered '1'	System	09 Oct 2020 13:15:40

US3222004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:29:46

US3222004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered '24 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:29:46

US3222004

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:29:46

US3222004
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:29:46

US3222004
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:29:51

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '1'	(b) (4), (b) (6) System	13 Oct 2020 13:29:51

US3222004
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:30:02

US3222004

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered '1 Oct 2020'	Albert Garcia (b) (4)	13 Oct 2020 13:30:02
	(b) (4)	

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:30:02

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US3222004
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:30:02

US3222004
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	13 Oct 2020 13:30:08

US3222004
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '1'	(b) (4), (b) (6) System	13 Oct 2020 13:30:08

US3222004
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:56:36

US3222004
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '08 Oct 2020' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 19:29:01
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 15:21:14
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'CORRECT AS ENTERED' (Site from System).	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:56:53
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	19 Oct 2020 18:56:36
User entered '19 Oct 2020'	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:56:36

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US3222004

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:56:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:20
User entered 'VISIT3'	(b) (4), (b) (6) System	19 Oct 2020 18:56:36

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Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:01

FDA-CBER-2022-1614-3553623

US3222004
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:01

FDA-CBER-2022-1614-3553624

US3222004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:01

US3222004
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:20
User entered empty.	(b) (4), (b) (6) System	19 Oct 2020 18:57:01

US3222004
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:01

US3222004

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:01

US3222004
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:01

US3222004
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:01

US3222004
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:20
User entered empty.	(b) (4), (b) (6) System	19 Oct 2020 18:57:01

US3222004
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:01

FDA-CBER-2022-1614-3553632

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:20
User entered empty.	(b) (4), (b) (6) System	19 Oct 2020 18:57:01

FDA-CBER-2022-1614-3553633

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:01

FDA-CBER-2022-1614-3553634

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:20
User entered empty.	(b) (4), (b) (6) System	19 Oct 2020 18:57:01

FDA-CBER-2022-1614-3553635

US3222004
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:20
User entered empty.	(b) (4), (b) (6) System	19 Oct 2020 18:57:01

FDA-CBER-2022-1614-3553637

US3222004
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20

US3222004

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:07

US3222004

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) / (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) / (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) / (b) (4)	19 Oct 2020 18:57:07

US3222004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:20
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	19 Oct 2020 18:57:18
	(b) (4)	

US3222004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query 'Per GCL Lab Reconciliation:Antibody-mediated Immunogenicity: Per response "Data will be corrected", please verify which data needs to updated and by when can it be expected to be updated.Thanks' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:14:00
Query 'Per GCL Lab Reconciliation:Antibody-mediated Immunogenicity: Per response "Data will be corrected", please verify which data needs to updated and by when can it be expected to be updated.Thanks' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 19:29:32
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	10 Nov 2020 19:29:12
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	10 Nov 2020 19:29:12
User entered '08 Oct 2020' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 19:29:12
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	10 Nov 2020 19:29:01
User opened query 'Per GCL Lab Reconciliation:Antibody-mediated Immunogenicity: Per response "Data will be corrected", please verify which data needs to updated and by when can it be expected to be updated.Thanks' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:41:52
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19OCT2020 is recorded under Visit 3 Day 57 in EDC; however, the same is reported under Visit 3 Day 57 with date 08OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:41:52

FDA-CBER-2022-1614-3553643

US3222004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19OCT2020 is recorded under Visit 3 Day 57 in EDC; however, the same is reported under Visit 3 Day 57 with date 08OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate, else clarify.' answered with 'DATA WILL BE CORRECTED. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	23 Oct 2020 13:10:04
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19OCT2020 is recorded under Visit 3 Day 57 in EDC; however, the same is reported under Visit 3 Day 57 with date 08OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:08:03
User entered '19 Oct 2020'	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:18

US3222004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '14:15'	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:18

US3222004

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:20
User entered '08 Oct 2020 14:15'	System	10 Nov 2020 19:29:12
User entered '19 Oct 2020 14:15'	System	19 Oct 2020 18:57:18

US3222004
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	19 Oct 2020 18:57:22

US3222004
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '1'	(b) (4), (b) (6) System	19 Oct 2020 18:57:22

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 64'	System	06 Aug 2020 14:21:14

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please 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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please 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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49
Data entry locked.	System	06 Aug 2020 14:21:14
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 14:21:14

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49
Data entry locked.	System	06 Aug 2020 14:21:14
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 71'	System	06 Aug 2020 14:21:14

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please 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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49
Data entry locked.	System	06 Aug 2020 14:21:14
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 14:21:14

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49
Data entry locked.	System	06 Aug 2020 14:21:14
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 78'	System	06 Aug 2020 14:21:14

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please 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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

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US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please 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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:14:23
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49
Data entry locked.	System	06 Aug 2020 14:21:14
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 14:21:14

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:12:49
Data entry locked.	System	06 Aug 2020 14:21:14
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 92'	System	06 Aug 2020 14:21:14

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-11-03T19:45:37', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '48512670-84ac-4cf2-845d-db8d2d19233b'	System	04 Nov 2020 00:45:59
User entered 'No (N)'	System	04 Nov 2020 00:45:59

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-11-03T19:45:43', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '48512670-84ac-4cf2-845d-db8d2d19233b'	System	04 Nov 2020 00:45:59
User entered 'No (N)'	System	04 Nov 2020 00:45:59

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-11-03T19:45:54', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '48512670-84ac-4cf2-845d-db8d2d19233b'	System	04 Nov 2020 00:45:59
User entered '03 Nov 2020 19:45:54'	System	04 Nov 2020 00:45:59

Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 14:21:14

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 99'	System	06 Aug 2020 14:21:14

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-11-12T16:49:53', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '4782f695-ac33-44d8-b191-0805d9a67606'	System	12 Nov 2020 21:50:19
User entered 'No (N)'	System	12 Nov 2020 21:50:19

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-11-12T16:50:01', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '4782f695-ac33-44d8-b191-0805d9a67606'	System	12 Nov 2020 21:50:19
User entered 'No (N)'	System	12 Nov 2020 21:50:19

US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-11-12T16:50:15', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '4782f695-ac33-44d8-b191-0805d9a67606'	System	12 Nov 2020 21:50:19
User entered '12 Nov 2020 16:50:15'	System	12 Nov 2020 21:50:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 14:21:14

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US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 14:21:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered 'Day 106'	System	06 Aug 2020 14:21:14

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-11-18T12:15:10', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6dfb262d-1e1a-4501-a756-f2ceccd4356b'	System	18 Nov 2020 17:15:23
User entered 'No (N)'	System	18 Nov 2020 17:15:23

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-11-18T12:15:14', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6dfb262d-1e1a-4501-a756-f2ceccd4356b'	System	18 Nov 2020 17:15:23
User entered 'No (N)'	System	18 Nov 2020 17:15:23

US3222004

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-11-18T12:15:19', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6dfb262d-1e1a-4501-a756-f2ceccd4356b'	System	18 Nov 2020 17:15:23
User entered '18 Nov 2020 12:15:19'	System	18 Nov 2020 17:15:23

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 14:21:14

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US3222004
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:58
Data entry locked.	System	06 Aug 2020 14:21:14
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 14:21:14

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2020-11-25T08:10:03', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'cbfe61fe-b80f-4852-bd3b-0f85e076878e'	System	25 Nov 2020 13:10:20
User entered 'No (N)'	System	25 Nov 2020 13:10:20

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2020-11-25T08:10:09', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'cbfe61fe-b80f-4852-bd3b-0f85e076878e'	System	25 Nov 2020 13:10:20
User entered 'No (N)'	System	25 Nov 2020 13:10:20

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-11-25T08:10:18', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'cbfe61fe-b80f-4852-bd3b-0f85e076878e'	System	25 Nov 2020 13:10:20
User entered '25 Nov 2020 08:10:18'	System	25 Nov 2020 13:10:20

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2020-12-09T09:18:51', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '3e34d1d1-3767-4db6-aa55-2a00a619c686'	System	09 Dec 2020 14:19:31
User entered 'No (N)'	System	09 Dec 2020 14:19:31

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2020-12-09T09:18:58', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '3e34d1d1-3767-4db6-aa55-2a00a619c686'	System	09 Dec 2020 14:19:31
User entered 'Yes (Y)'	System	09 Dec 2020 14:19:31

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-12-09T09:19:07', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '3e34d1d1-3767-4db6-aa55-2a00a619c686'	System	09 Dec 2020 14:19:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Dec 2020 14:19:31

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-12-09T09:19:18', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '3e34d1d1-3767-4db6-aa55-2a00a619c686'	System	09 Dec 2020 14:19:31
User entered '09 Dec 2020 09:19:18'	System	09 Dec 2020 14:19:31

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:12:49

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:12:49

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2020-12-23T14:58:58', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6d0d82ba-7557-4139-bacf-68594846044d'	System	23 Dec 2020 19:59:12
User entered 'No (N)'	System	23 Dec 2020 19:59:12

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2020-12-23T14:59:02', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6d0d82ba-7557-4139-bacf-68594846044d'	System	23 Dec 2020 19:59:12
User entered 'No (N)'	System	23 Dec 2020 19:59:12

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-12-23T14:59:07', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6d0d82ba-7557-4139-bacf-68594846044d'	System	23 Dec 2020 19:59:12
User entered '23 Dec 2020 14:59:07'	System	23 Dec 2020 19:59:12

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2020-12-28T12:20:55', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8b0ccb2b-590b-4dd8-9c8d-629ecaabae03'	System	28 Dec 2020 17:21:09
User entered 'No (N)'	System	28 Dec 2020 17:21:09

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2020-12-28T12:21:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8b0ccb2b-590b-4dd8-9c8d-629ecaabae03'	System	28 Dec 2020 17:21:09
User entered 'No (N)'	System	28 Dec 2020 17:21:09

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2020-12-28T12:21:04', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8b0ccb2b-590b-4dd8-9c8d-629ecaabae03'	System	28 Dec 2020 17:21:09
User entered '28 Dec 2020 12:21:04'	System	28 Dec 2020 17:21:09

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-01-04T08:48:25', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'dc4688bb-fdbb-4dae-bb68-cd0b48a37e38'	System	04 Jan 2021 13:48:38
User entered 'No (N)'	System	04 Jan 2021 13:48:38

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-01-04T08:48:29', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'dc4688bb-fdbb-4dae-bb68-cd0b48a37e38'	System	04 Jan 2021 13:48:38
User entered 'No (N)'	System	04 Jan 2021 13:48:38

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-01-04T08:48:33', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'dc4688bb-fdbb-4dae-bb68-cd0b48a37e38'	System	04 Jan 2021 13:48:38
User entered '04 Jan 2021 08:48:33'	System	04 Jan 2021 13:48:38

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-01-09T09:07:12', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a6ca1229-41c5-493f-9c55-c9183c212309'	System	09 Jan 2021 14:07:26
User entered 'No (N)'	System	09 Jan 2021 14:07:26

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-01-09T09:07:17', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a6ca1229-41c5-493f-9c55-c9183c212309'	System	09 Jan 2021 14:07:26
User entered 'No (N)'	System	09 Jan 2021 14:07:26

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-01-09T09:07:22', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'a6ca1229-41c5-493f-9c55-c9183c212309'	System	09 Jan 2021 14:07:26
User entered '09 Jan 2021 09:07:22'	System	09 Jan 2021 14:07:26

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:12:49

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US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-01-24T19:39:55', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '13234db2-d69d-4961-9282-3ac24f7a5cc5'	System	25 Jan 2021 00:40:21
User entered 'No (N)'	System	25 Jan 2021 00:40:21

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-01-24T19:39:59', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '13234db2-d69d-4961-9282-3ac24f7a5cc5'	System	25 Jan 2021 00:40:21
User entered 'No (N)'	System	25 Jan 2021 00:40:21

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-01-24T19:40:16', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '13234db2-d69d-4961-9282-3ac24f7a5cc5'	System	25 Jan 2021 00:40:21
User entered '24 Jan 2021 19:40:16'	System	25 Jan 2021 00:40:21

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:12:49

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-02-02T19:40:53', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6c41f9bc-ff6c-4a59-b778-e18dd1eb5eca'	System	03 Feb 2021 00:41:09
User entered 'No (N)'	System	03 Feb 2021 00:41:09

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-02-02T19:41:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6c41f9bc-ff6c-4a59-b778-e18dd1eb5eca'	System	03 Feb 2021 00:41:09
User entered 'No (N)'	System	03 Feb 2021 00:41:09

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-02-02T19:41:04', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '6c41f9bc-ff6c-4a59-b778-e18dd1eb5eca'	System	03 Feb 2021 00:41:09
User entered '02 Feb 2021 19:41:04'	System	03 Feb 2021 00:41:09

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-02-06T19:01:22', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '3ba4df9f-327c-48c3-b918-4b264b12506e'	System	07 Feb 2021 00:02:58
User entered 'No (N)'	System	07 Feb 2021 00:02:58

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-02-06T19:01:25', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '3ba4df9f-327c-48c3-b918-4b264b12506e'	System	07 Feb 2021 00:02:58
User entered 'No (N)'	System	07 Feb 2021 00:02:58

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-02-06T19:01:38', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '3ba4df9f-327c-48c3-b918-4b264b12506e'	System	07 Feb 2021 00:02:58
User entered '06 Feb 2021 19:01:38'	System	07 Feb 2021 00:02:58

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:12:49

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-02-13T09:30:18', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'c43e2545-178d-47a3-aea7-5b07e295fdc1'	System	13 Feb 2021 14:30:36
User entered 'No (N)'	System	13 Feb 2021 14:30:36

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-02-13T09:30:24', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'c43e2545-178d-47a3-aea7-5b07e295fdc1'	System	13 Feb 2021 14:30:36
User entered 'No (N)'	System	13 Feb 2021 14:30:36

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-02-13T09:30:28', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'c43e2545-178d-47a3-aea7-5b07e295fdc1'	System	13 Feb 2021 14:30:36
User entered '13 Feb 2021 09:30:28'	System	13 Feb 2021 14:30:36

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:12:49

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-02-23T08:40:41', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e3850c6b-65e7-463b-9bc6-d26059f7d9a1'	System	23 Feb 2021 13:40:54
User entered 'No (N)'	System	23 Feb 2021 13:40:54

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-02-23T08:40:46', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e3850c6b-65e7-463b-9bc6-d26059f7d9a1'	System	23 Feb 2021 13:40:54
User entered 'No (N)'	System	23 Feb 2021 13:40:54

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-02-23T08:40:50', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'e3850c6b-65e7-463b-9bc6-d26059f7d9a1'	System	23 Feb 2021 13:40:54
User entered '23 Feb 2021 08:40:50'	System	23 Feb 2021 13:40:54

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-02-28T21:17:36-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7834a544-e3c9-4305-90ef-cef9f925089e'	System	01 Mar 2021 02:28:23
User entered 'No (N)'	System	01 Mar 2021 02:28:23

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-02-28T21:17:40-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7834a544-e3c9-4305-90ef-cef9f925089e'	System	01 Mar 2021 02:28:23
User entered 'No (N)'	System	01 Mar 2021 02:28:23

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-02-28T21:17:47-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7834a544-e3c9-4305-90ef-cef9f925089e'	System	01 Mar 2021 02:28:23
User entered '28 Feb 2021 21:17:47'	System	01 Mar 2021 02:28:23

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-03-08T08:57:13-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '82b55415-7de5-4cd9-b701-e476385bc16e'	System	08 Mar 2021 13:57:26
User entered 'No (N)'	System	08 Mar 2021 13:57:26

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-03-08T08:57:16-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '82b55415-7de5-4cd9-b701-e476385bc16e'	System	08 Mar 2021 13:57:26
User entered 'No (N)'	System	08 Mar 2021 13:57:26

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-03-08T08:57:22-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '82b55415-7de5-4cd9-b701-e476385bc16e'	System	08 Mar 2021 13:57:26
User entered '08 Mar 2021 08:57:22'	System	08 Mar 2021 13:57:26

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-03-13T10:43:05-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7af903c8-e440-4d6c-b29a-20f823c26117'	System	13 Mar 2021 15:45:25
User entered 'Yes (Y)'	System	13 Mar 2021 15:45:25

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-03-13T10:42:33-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7af903c8-e440-4d6c-b29a-20f823c26117'	System	13 Mar 2021 15:45:25
User entered 'No (N)'	System	13 Mar 2021 15:45:25

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-03-13T10:42:44-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7af903c8-e440-4d6c-b29a-20f823c26117'	System	13 Mar 2021 15:45:25
User entered 'No (N)'	System	13 Mar 2021 15:45:25

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-03-13T10:42:50-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7af903c8-e440-4d6c-b29a-20f823c26117'	System	13 Mar 2021 15:45:25
User entered 'No (N)'	System	13 Mar 2021 15:45:25

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-03-13T10:45:22-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7af903c8-e440-4d6c-b29a-20f823c26117'	System	13 Mar 2021 15:45:25
User entered '13 Mar 2021 10:45:22'	System	13 Mar 2021 15:45:25

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-03-22T08:05:37-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8016e478-c672-497f-98ce-5f04038e5d41'	System	22 Mar 2021 12:05:49
User entered 'No (N)'	System	22 Mar 2021 12:05:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-03-22T08:05:40-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8016e478-c672-497f-98ce-5f04038e5d41'	System	22 Mar 2021 12:05:49
User entered 'No (N)'	System	22 Mar 2021 12:05:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-03-22T08:05:44-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8016e478-c672-497f-98ce-5f04038e5d41'	System	22 Mar 2021 12:05:49
User entered '22 Mar 2021 08:05:44'	System	22 Mar 2021 12:05:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-03-29T09:28:58-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'ef1c71a0-b3fa-4473-b530-ff2b6e3c32f2'	System	29 Mar 2021 13:29:14
User entered 'No (N)'	System	29 Mar 2021 13:29:14

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-03-29T09:29:06-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'ef1c71a0-b3fa-4473-b530-ff2b6e3c32f2'	System	29 Mar 2021 13:29:14
User entered 'No (N)'	System	29 Mar 2021 13:29:14

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-03-29T09:29:10-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: 'ef1c71a0-b3fa-4473-b530-ff2b6e3c32f2'	System	29 Mar 2021 13:29:14
User entered '29 Mar 2021 09:29:10'	System	29 Mar 2021 13:29:14

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:12:49

FDA-CBER-2022-1614-3553858

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:12:49

FDA-CBER-2022-1614-3553859

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-04-03T09:31:12-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8a582703-9c25-46cb-bef2-d16201a2d4b2'	System	03 Apr 2021 13:31:25
User entered 'No (N)'	System	03 Apr 2021 13:31:25

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-04-03T09:31:16-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8a582703-9c25-46cb-bef2-d16201a2d4b2'	System	03 Apr 2021 13:31:25
User entered 'No (N)'	System	03 Apr 2021 13:31:25

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-04-03T09:31:20-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8a582703-9c25-46cb-bef2-d16201a2d4b2'	System	03 Apr 2021 13:31:25
User entered '03 Apr 2021 09:31:20'	System	03 Apr 2021 13:31:25

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-04-11T09:25:24-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7004cc27-29d0-4486-9ec2-006f7ba2356a'	System	11 Apr 2021 13:25:37
User entered 'No (N)'	System	11 Apr 2021 13:25:37

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-04-11T09:25:28-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7004cc27-29d0-4486-9ec2-006f7ba2356a'	System	11 Apr 2021 13:25:37
User entered 'No (N)'	System	11 Apr 2021 13:25:37

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-04-11T09:25:32-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7004cc27-29d0-4486-9ec2-006f7ba2356a'	System	11 Apr 2021 13:25:37
User entered '11 Apr 2021 09:25:32'	System	11 Apr 2021 13:25:37

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-04-17T21:58:19-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8aeee4b9-fbbc-436d-81e0-98afd57df3e5'	System	18 Apr 2021 01:58:33
User entered 'No (N)'	System	18 Apr 2021 01:58:33

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-04-17T21:58:23-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8aeee4b9-fbbc-436d-81e0-98afd57df3e5'	System	18 Apr 2021 01:58:33
User entered 'No (N)'	System	18 Apr 2021 01:58:33

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-04-17T21:58:27-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8aeee4b9-fbbc-436d-81e0-98afd57df3e5'	System	18 Apr 2021 01:58:33
User entered '17 Apr 2021 21:58:27'	System	18 Apr 2021 01:58:33

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02

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 (009f8d8845460930)', Time: '2021-04-25T12:00:25-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7dfd5bb3-9b8b-4ac0-aa9c-2b8b4f161007'	System	28 Apr 2021 22:40:49
User entered 'No (N)'	System	28 Apr 2021 22:40:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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 (009f8d8845460930)', Time: '2021-04-28T14:21:22-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7dfd5bb3-9b8b-4ac0-aa9c-2b8b4f161007'	System	28 Apr 2021 22:40:49
User entered 'No (N)'	System	28 Apr 2021 22:40:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-04-28T14:21:30-04:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '7dfd5bb3-9b8b-4ac0-aa9c-2b8b4f161007'	System	28 Apr 2021 22:40:49
User entered '28 Apr 2021 14:21:30'	System	28 Apr 2021 22:40:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:12:49

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:12:49

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:12:49

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:12:49

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:12:49

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:12:49

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:12:49

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:12:49

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:12:49

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Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:12:49

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Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:12:49

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:12:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:12:49

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:12:49

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US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:12:49

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:12:49

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:12:49

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:12:49

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:12:49

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:12:49

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:12:49

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US3222004

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:12:49

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:12:49

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:12:49

US3222004
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 16:02:02
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:12:49
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:12:49

US3222004

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:02:02

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) (b) (4), (b) (6)	25 Apr 2021 06:14:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-02-28T21:17:59-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8d7bc9c3-4d37-46a8-8077-70c2539873b5'	System	01 Mar 2021 02:28:30
User entered 'No (N)'	System	01 Mar 2021 02:28:30

US3222004

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:02:02

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Apr 2021 06:14:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (009f8d8845460930)', Time: '2021-02-28T21:18:03-05:00', User OID: 'PatientReportedOutcome (US3222004)', ODM File OID: '8d7bc9c3-4d37-46a8-8077-70c2539873b5'	System	01 Mar 2021 02:28:30
User entered '28 Feb 2021 21:18:03'	System	01 Mar 2021 02:28:30

US3222004
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 19:25:55

US3222004
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:54:25
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'DATE IS CORRECT AS ENTERED' (Site from System).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 19:27:04
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Nov 2020 19:25:55
User entered '30 Oct 2020'	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 19:25:55

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Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 19:25:55

US3222004
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 19:25:55

US3222004
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	10 Nov 2020 19:27:13

US3222004
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:37:19
User entered '1'	(b) (4), (b) (6) System	10 Nov 2020 19:27:13

US3222004
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:25:42
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	heather jackson (b) (4) (b) (4)	08 Dec 2020 21:32:04

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US3222004
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:25:42
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered '08 Dec 2020'	heather jackson (b) (4)	08 Dec 2020 21:32:04
	(b) (4)	

US3222004
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 10:25:42
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4) (b) (4)	08 Dec 2020 21:32:04

US3222004
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:25:42
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered empty.	heather jackson (b) (4)	08 Dec 2020 21:32:04
	(b) (4)	

US3222004
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:25:42
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	(b) (4) heather jackson (b) (4) (b) (4)	08 Dec 2020 21:32:09

US3222004
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:25:42
User entered '1'	(b) (4), (b) (6) System	08 Dec 2020 21:32:09

US3222004
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:25:42
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) heather jackson (b) (4) (b) (4)	31 Dec 2020 16:52:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 20:50:22
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	gail lavine (b) (4) (b) (4)	15 Dec 2020 14:13:25
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 14:13:10
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	15 Dec 2020 14:13:10
User entered empty; reason for change Data Entry Error	gail lavine (b) (4) (b) (4)	15 Dec 2020 14:13:10
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	15 Dec 2020 14:13:01
User entered 'Yes (Y)'	gail lavine (b) (4) (b) (4)	15 Dec 2020 14:11:58

US3222004
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 10:25:42
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	05 Jan 2021 16:28:10
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	05 Jan 2021 16:28:10
User entered '05 Jan 2021' reason for change: Data Entry Error	heather jackson (b) (4) (b) (4)	05 Jan 2021 16:28:10
User entered '02 Jan 2021' reason for change: Data Entry Error	heather jackson (b) (4) (b) (4)	05 Jan 2021 16:28:02
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	31 Dec 2020 16:52:58
User entered '31 Dec 2020' reason for change: Data Entry Error	heather jackson (b) (4) (b) (4)	31 Dec 2020 16:52:58
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	15 Dec 2020 14:13:01
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	15 Dec 2020 14:13:01
User entered empty; reason for change Data Entry Error	gail lavine (b) (4) (b) (4)	15 Dec 2020 14:13:01
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	15 Dec 2020 14:11:58

US3222004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User entered '08 Dec 2020'	gail lavine (b) (4) (b) (4)	15 Dec 2020 14:11:58

US3222004

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:25:42
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	heather jackson (b) (4)	31 Dec 2020 16:52:58
User entered empty; reason for change Data Entry Error	gail lavine (b) (4)	15 Dec 2020 14:13:01
User entered 'Contact Made (CONTACT MADE)'	gail lavine (b) (4)	15 Dec 2020 14:11:58

US3222004
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 10:25:42
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	gail lavine (b) (4) (b) (4)	15 Dec 2020 14:11:58

US3222004
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 10:25:42
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)' reason for change: Data Entry Error	heather jackson (b) (4) (b) (4)	05 Jan 2021 16:28:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 20:50:37
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	gail lavine (b) (4) (b) (4)	15 Dec 2020 14:13:43
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 14:13:33
User entered empty; reason for change Data Entry Error	gail lavine (b) (4) (b) (4)	15 Dec 2020 14:13:33
User entered 'Yes (Y)'	gail lavine (b) (4) (b) (4)	15 Dec 2020 14:12:12

US3222004
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 10:25:42
User entered '1'	System	05 Jan 2021 16:28:15
User entered empty.	System	15 Dec 2020 14:13:33
User entered '1'	System	15 Dec 2020 14:12:12

US3222004
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:25:42
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:10:02
	(b) (4)	
User entered 'Yes (Y)'	Diana Toney (b) (4)	16 Mar 2021 22:17:00
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:25:42
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:10:02
User entered '04 Feb 2021'	Diana Toney (b) (4)	16 Mar 2021 22:17:00

FDA-CBER-2022-1614-3554133

US3222004
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:25:42
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered 'Contact Made (CONTACT MADE)'	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:17:00

FDA-CBER-2022-1614-3554134

US3222004
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 10:25:42
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered empty.	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:17:00

US3222004
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 10:25:42
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:17:06

US3222004
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:25:42
User entered '1'	(b) (4), (b) (6) System	16 Mar 2021 22:17:06

US3222004
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:17:34

US3222004
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered '15 Mar 2021'	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:17:34

US3222004
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered 'Clinic (Clinic)'	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:17:34

US3222004
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered 'VISIT4'	System	16 Mar 2021 22:17:34

US3222004

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	05 Apr 2021 20:09:28
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 13:19:55

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	05 Apr 2021 20:09:28
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 13:19:55

FDA-CBER-2022-1614-3554143

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	05 Apr 2021 20:09:28
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 13:19:55

FDA-CBER-2022-1614-3554144

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	31 Mar 2021 13:19:55

US3222004
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	05 Apr 2021 20:09:28
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 13:19:55

US3222004
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	05 Apr 2021 20:09:28
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 13:19:55

US3222004
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	05 Apr 2021 20:09:28
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 13:19:55

US3222004
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	05 Apr 2021 20:09:28
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 13:19:55

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	31 Mar 2021 13:19:55

US3222004
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	05 Apr 2021 20:09:28
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 13:19:55

US3222004
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	31 Mar 2021 13:19:55

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	05 Apr 2021 20:09:28
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 13:19:55

US3222004
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	31 Mar 2021 13:19:55

US3222004
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	05 Apr 2021 20:09:28
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 13:19:55

US3222004
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered empty.	System	31 Mar 2021 13:19:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18

US3222004
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 16:02:02
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18

US3222004

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered 'No (N)'	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:18:15

US3222004

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered empty.	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:18:15

US3222004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:18:31

US3222004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered '15 Mar 2021'	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:18:31

US3222004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered '12:40'	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:18:31

US3222004

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '15 Mar 2021 12:40'	System	16 Mar 2021 22:18:31

US3222004
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered 'Yes (Y)'	Diana Toney (b) (4) (b) (4)	16 Mar 2021 22:18:35

US3222004
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 06:57:18
User entered '1'	System	16 Mar 2021 22:18:35

US3222004
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:45:25
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	05 Apr 2021 20:09:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:40:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:45:25
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	05 Apr 2021 20:09:28
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:40:26

US3222004

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 04:45:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	05 Apr 2021 20:09:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Apr 2021 17:40:26

US3222004
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 16:02:02
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:45:25
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	05 Apr 2021 20:09:28
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:40:26

US3222004
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:45:25
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	05 Apr 2021 20:09:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:40:31

US3222004
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 16:02:02
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:45:25
User entered '1'	(b) (4), (b) (6) System	05 Apr 2021 17:40:31

US3222004
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 13:48:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered '17 Jan 2021'	(b) (4), (b) (6)	17 Jan 2021 13:48:14

FDA-CBER-2022-1614-3554174

US3222004

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

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 13:48:14

US3222004
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 16:02:02
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	17 Jan 2021 13:48:14

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '17 Jan 2021'	(b) (4), (b) (6)	17 Jan 2021 13:48:32

FDA-CBER-2022-1614-3554177

US3222004

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	26 Apr 2021 13:33:39
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:29:58
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:27:57

US3222004

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Jan 2021 13:48:32

US3222004

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	26 Apr 2021 13:33:39
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) (4), (b) (6)	23 Apr 2021 20:10:10
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 12:30:14
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	22 Apr 2021 12:29:58
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)	22 Apr 2021 07:07:51
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:27:57

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '17 Jan 2021'	(b) (4), (b) (6)	17 Jan 2021 13:48:32

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	17 Jan 2021 13:48:32

US3222004

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	Bruce Rankin (b) (4), (b) (6) (b) (4)	16 Feb 2021 16:25:57
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 01:17:04
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	17 Jan 2021 13:48:32

US3222004

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 01:17:04
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	17 Jan 2021 13:48:32

FDA-CBER-2022-1614-3554184

US3222004

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

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 13:48:32

US3222004
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:02:02
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User entered empty.	(b) (4), (b) (6) System	17 Jan 2021 13:48:32

US3222004
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 16:02:02
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User entered empty.	(b) (4), (b) (6) System	17 Jan 2021 13:48:32

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 13:48:46

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
	(b) (4), (b) (6)	
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered '17 Jan 2021'	(b) (4), (b) (6)	17 Jan 2021 13:48:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered '7:55'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 13:48:46

US3222004

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User entered '17 Jan 2021 7:55'	(b) (4), (b) (6) System	17 Jan 2021 13:48:46

US3222004

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 13:48:57

US3222004

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:02:02

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '17 Jan 2021'	(b) (4), (b) (6)	17 Jan 2021 13:48:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User signature succeeded.	(b) (4), (b) (6) Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered '7:58'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 13:48:57

US3222004

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:02:02

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:02
User entered '17 Jan 2021 7:58'	(b) (4), (b) (6) System	17 Jan 2021 13:48:57

US3222004

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:02:02

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:00
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:29
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 18:57:04
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	06 Aug 2020 15:47:08

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
AEID

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:49
User entered 'USA-US104-2020-mRNA-1273-P301000011'	System	12 Oct 2020 14:09:45
User entered 'New'	(b) (4), (b) (6)	12 Oct 2020 14:09:45

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Uncontrolled hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:08:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:08:55
Data point term sent to Coder	System	30 Oct 2020 16:51:45
Coding entries removed.	douglas winter (b) (4) (b) (4)	30 Oct 2020 16:51:04
User entered 'UNCONTROLLED HYPERTENSION' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Oct 2020 16:51:04
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:26:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:26:28
Data point term sent to Coder	System	09 Oct 2020 19:25:50
User entered 'HYPERTENSION'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered '1 Oct 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered '2 Oct 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Severity

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered 'Grade 4 (Grade 4)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Oct 2020 19:26:04
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Oct 2020 19:25:07
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

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US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	09 Oct 2020 19:26:04
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	09 Oct 2020 19:26:04
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:26:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	09 Oct 2020 19:25:07
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered '1 Oct 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered '2 Oct 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered '0'	douglas winter (b) (4)	09 Oct 2020 19:25:07
	(b) (4)	

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User closed query 'PV Query: As the last dose of study drug was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 18:53:02
Query 'PV Query: As the last dose of study drug was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 13:28:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	16 Oct 2020 13:28:19
User opened query 'PV Query: As the last dose of study drug was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:18:44
User entered 'None (NONE)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Oct 2020 19:26:04
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Oct 2020 19:25:07
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:26:04
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User closed query 'Per DM CLR: Other action taken = Concomitant Procedure. Please disregard query in Con procedure, please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 08:49:43
Query 'Per DM CLR: Other action taken = Concomitant Procedure. Please disregard query in Con procedure, please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field.' answered with 'updated per query' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 16:32:26
Signature has been broken.	(b) (4), (b) (6)	08 Mar 2021 16:32:09
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Mar 2021 16:32:09
User opened query 'Per DM CLR: Other action taken = Concomitant Procedure. Please disregard query in Con procedure, please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 04:05:06
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:05:53
DataPoint Un-verified.	Amber Vasquez (b) (4) (b) (4)	04 Mar 2021 14:02:26
Signature has been broken.	Amber Vasquez (b) (4) (b) (4)	04 Mar 2021 14:02:26
User entered '1' reason for change: Data Entry Error	Amber Vasquez (b) (4) (b) (4)	04 Mar 2021 14:02:26
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered '0'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User closed query 'Per DM CLR: SAE Narrative = TROPONINS WERE NEGATIVE, SHE HAD A 2D ECHO, AND STRESS TEST. However, these were not recorded in the ConProc eCRF. Please review and ensure that these were captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:06:48
User closed query 'Per DM CLR: SAE Narrative = SHE WAS PRESCRIBED LOSARTAN 25 MCG. However, this medication is not typically given in micrograms. Please review and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:06:45
Query 'Per DM CLR: SAE Narrative = TROPONINS WERE NEGATIVE, SHE HAD A 2D ECHO, AND STRESS TEST. However, these were not recorded in the ConProc eCRF. Please review and ensure that these were captured in the appropriate eCRF. ' answered with 'PROCEDURES HAVE BEEN UPDATED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	01 Dec 2020 20:58:51
Query 'Per DM CLR: SAE Narrative = SHE WAS PRESCRIBED LOSARTAN 25 MCG. However, this medication is not typically given in micrograms. Please review and update as appropriate. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	01 Dec 2020 20:49:05
DataPoint Un-verified.	Alicia Cevera (b) (4) (b) (4)	01 Dec 2020 20:48:52
User entered 'THIS SAE WAS SUBMITTED THE SAME DAY 05/OCT/2020 VIA EMAIL. PATIENT CALLED ME TODAY 05/OCT/2020 @ 13:01 TO TELL ME SHE WAS IN THE HOSPITAL FOR HYPERTENSION. ADMISSION 01/OCT/2020 FOR CHEST PRESSURE WITH ELEVATED BLOOD PRESSURE. HER TROPONINS WERE NEGATIVE, SHE HAD A 2D ECHO, AND STRESS TEST AND SHE WAS PRESCRIBED LOSARTAN 25 MG AT DISCHARGE. SHE WILL FOLLOW-UP WITH HER PCP (WHOM IS OUR SUB-I ON THIS TRIAL) IN 1-2 WEEKS.' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	01 Dec 2020 20:48:52

PRODUCTION RELEASE (v12.003 EAB) (1725)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = SHE WAS PRESCRIBED LOSARTAN 25 MCG. However, this medication is not typically given in micrograms. Please review and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:32:43
User opened query 'Per DM CLR: SAE Narrative = TROPONINS WERE NEGATIVE, SHE HAD A 2D ECHO, AND STRESS TEST. However, these were not recorded in the ConProc eCRF. Please review and ensure that these were captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:32:35
User closed query 'PV Query: Please provide results of 2D ECHO and stress test.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 15:41:33
Query 'PV Query: Please provide results of 2D ECHO and stress test.' answered with 'ECHO AND STRESS TST WERE NOT PROVIDED AS PART OF THE DISCHARGE SUMMARY. ' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 19:31:58
User opened query 'PV Query: Please provide results of 2D ECHO and stress test.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 13:24:24
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:35
User closed query 'PV Query: Please update the EDC with the information from the paper SAE form including its relevant details, hospitalization details and course of event.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:53:19
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:53:11
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:52:59
User closed query 'PV Query: Please provide the patient's blood pressure at the time of admission and on discharge.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:52:51

US3222004

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm the sex and date of birth for this subject. The paper SAE form does not match the demographic page.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:52:37
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:52:13
User closed query 'PV Query: Please provide patient's signs/symptoms .' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:52:02
User closed query 'PV Query: Please report if there were any risk factors or triggers that may have caused hypertension (i.e. diet high in sodium, obesity, cardiovascular disease, renal disease, previous history of hypertension, emotional stress, etc)' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:51:23
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'I UPDATED THE MEDICATION LIST AND MEDICAL HISTORY' (Site from Safety).	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:08:20
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'NOT STATED IN DISCHARGE SUMMARY' (Site from Safety).	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:06:52
Query 'PV Query: Please report if there were any risk factors or triggers that may have caused hypertension (i.e. diet high in sodium, obesity, cardiovascular disease, renal disease, previous history of hypertension, emotional stress, etc)' answered with 'CARDIAC HISTORY ATRIAL FLUTTER DEPRESSION FIBROMYALGIA ' (Site from Safety).	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:06:32

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the patient's blood pressure at the time of admission and on discharge.' answered with 'I ONLY HAVE HER DISCHARGE VITALS. B/P 127/70 SPO2 100% HR 79 TEMP 97.5 ' (Site from Safety).	douglas winter (b) (4) (b) (4)	30 Oct 2020 18:03:17
Query 'PV Query: Please provide patient's signs/symptoms .' answered with 'CHEST PAIN, UNCONTROLLED HYPERTENSION' (Site from Safety).	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:57:45
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'CHEST XR PER CARDIOLOGIST NO ACUTE CARDIOPULMONARY FINDINGS. 2D ECHO AND STRESS TEST STILL PENDING. TROPONINS WERE NEGATIVE.' (Site from Safety).	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:02:53
Query 'PV Query: Please confirm the sex and date of birth for this subject. The paper SAE form does not match the demographic page.' answered with 'FEMALE, (b) (6)/1951. I UNDATED THE PAPER SAE FORM WITH THE PATIENTS CORRECT INFORMATION AND RESUBMITTED TODAY.' (Site from Safety).	douglas winter (b) (4) (b) (4)	30 Oct 2020 16:58:57
Query 'PV Query: Please update the EDC with the information from the paper SAE form including its relevant details, hospitalization details and course of event.' answered with 'SAE UPDATED WITH FOLLOW-UP INFORMATION.' (Site from Safety).	douglas winter (b) (4) (b) (4)	30 Oct 2020 16:57:38

Audit	User	Time (GMT)
User entered 'THIS SAE WAS SUBMITTED THE SAME DAY 05/OCT/2020 VIA EMAIL. PATIENT CALLED ME TODAY 05/OCT/2020 @ 13:01 TO TELL ME SHE WAS IN THE HOSPITAL FOR HYPERTENSION. ADMISSION 01/OCT/2020 FOR CHEST PRESSURE WITH ELEVATED BLOOD PRESSURE. HER TROPONINS WERE NEGATIVE, SHE HAD A 2D ECHO, AND STRESS TEST AND SHE WAS PRESCRIBED LOSARTAN 25 MCG AT DISCHARGE. SHE WILL FOLLOW-UP WITH HER PCP (WHOM IS OUR SUB-I ON THIS TRIAL) IN 1-2 WEEKS.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Oct 2020 16:51:04
User opened query 'PV Query: Please provide patient's signs/symptoms .' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:14:46
User opened query 'PV Query: Please provide the patient's blood pressure at the time of admission and on discharge.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:14:41
User opened query 'PV Query: Please report if there were any risk factors or triggers that may have caused hypertension (i.e. diet high in sodium, obesity, cardiovascular disease, renal disease, previous history of hypertension, emotional stress, etc)' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:14:34
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:14:25
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:14:14
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:14:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm the sex and date of birth for this subject. The paper SAE form does not match the demographic page.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:13:59
User opened query 'PV Query: Please update the EDC with the information from the paper SAE form including its relevant details, hospitalization details and course of event.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:13:53
User closed query 'PV Query: Please provide patient's signs/symptoms .' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:46:08
User closed query 'PV Query: Please provide the patient's blood pressure at the time of admission and on discharge.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:46:05
User closed query 'PV Query: Please report if there were any risk factors or triggers that may have caused hypertension (i.e. diet high in sodium, obesity, cardiovascular disease, renal disease, previous history of hypertension, emotional stress, etc)' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:46:02
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:45:50
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:45:41
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:45:36
User closed query 'PV Query: Please confirm the sex and date of birth for this subject. The paper SAE form does not match the demographic page.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:45:31

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please update the EDC with the information from the paper SAE form including its relevant details, hospitalization details and course of event.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 19:45:25
Query 'PV Query: Please confirm the sex and date of birth for this subject. The paper SAE form does not match the demographic page.' answered with 'WILL BE RECONCILED' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 15:11:22
Query 'PV Query: Please provide the patient's blood pressure at the time of admission and on discharge.' answered with 'RECORDS HAVE BEEN REQUESTED' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 15:11:06
Query 'PV Query: Please provide patient's signs/symptoms .' answered with 'RECORDS HAVE BEEN REQUESTED' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 15:10:54
Query 'PV Query: Please report if there were any risk factors or triggers that may have caused hypertension (i.e. diet high in sodium, obesity, cardiovascular disease, renal disease, previous history of hypertension, emotional stress, etc)' answered with 'RECORDS HAVE BEEN REQUESTED' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 15:10:43
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'RECORDS HAVE BEEN REQUESTED' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 15:10:33
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'RECORDS HAVE BEEN REQUESTED' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 15:10:23
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'RECORDS HAVE BEEN REQUESTED' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 15:10:12

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please update the EDC with the information from the paper SAE form including its relevant details, hospitalization details and course of event.' answered with 'RECORDS HAVE BEEN REQUESTED' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 15:09:39
User opened query 'PV Query: Please provide patient's signs/symptoms .' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:19:51
User opened query 'PV Query: Please provide the patient's blood pressure at the time of admission and on discharge.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:19:42
User opened query 'PV Query: Please report if there were any risk factors or triggers that may have caused hypertension (i.e. diet high in sodium, obesity, cardiovascular disease, renal disease, previous history of hypertension, emotional stress, etc)' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:19:31
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:19:20
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:19:14
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:18:57
User opened query 'PV Query: Please confirm the sex and date of birth for this subject. The paper SAE form does not match the demographic page.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:18:22
User opened query 'PV Query: Please update the EDC with the information from the paper SAE form including its relevant details, hospitalization details and course of event.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:18:10

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Narrative

Audit	User	Time (GMT)
User entered 'THIS SAE WAS SUBMITTED THE SAME DAY 05/OCT/2020 VIA EMAIL. PATIENT CALLED ME TODAY 05/OCT/2020 @ 13:01 TO TELL ME SHE WAS IN THE HOSPITAL FOR HYPERTENSION.'	douglas winter (b) (4) (b) (4)	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:25:07

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:25:07

US3222004
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 16:02:02
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 19:25:07

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:00
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:07:36
User closed query 'Per ETRTR: According to SAE "Hypertension", medications was dosed. Please update CRF page with Medication dosed for SAE, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 16:07:33
Query 'Per ETRTR: According to SAE "Hypertension", medications was dosed. Please update CRF page with Medication dosed for SAE, thanks.' answered with 'RECORDS HAVE BEEN REQUESTED' (Site from CRA).	Albert Garcia (b) (4) (b) (4)	21 Oct 2020 15:11:59
User opened query 'Per ETRTR: According to SAE "Hypertension", medications was dosed. Please update CRF page with Medication dosed for SAE, thanks.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 23:51:28
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Aug 2020 20:44:24

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 21:09:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 21:09:47
Data point term sent to Coder	System	23 Aug 2020 21:09:03
User entered 'Ibuprofen'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Headaches'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '400'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'as needed (PRN)'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 16:02:02
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '1'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	23 Aug 2020 21:08:04

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:06:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:06:55
Data point term sent to Coder	System	30 Oct 2020 17:06:07
User entered 'LOSARTAN'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'HYPERTENSION'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '50' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	08 Feb 2021 12:58:54
User entered '25'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'mg (mg)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	24 Nov 2020 20:44:11
User entered 'ug (ug)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'once daily (QD)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '2 Oct 2020'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User closed query 'Per DM CLR: Please review status of AE#1 Hypertension if this indeed is not ongoing as this is unusual for a chronic condition to have a stop date. If AE#1 is confirmed with a stop date. Review if medication should have a corresponding stop date. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 09:10:17
Query 'Per DM CLR: Please review status of AE#1 Hypertension if this indeed is not ongoing as this is unusual for a chronic condition to have a stop date. If AE#1 is confirmed with a stop date. Review if medication should have a corresponding stop date. Else, provide clarification. ' answered with 'corrected Subject continues on the losartin for hypertension control' (Site from DM).	gail lavine (b) (4) (b) (4)	08 Feb 2021 13:03:41
User entered 'Yes (Y)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	08 Feb 2021 13:02:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 18:34:55
User opened query 'Per DM CLR: Please review status of AE#1 Hypertension if this indeed is not ongoing as this is unusual for a chronic condition to have a stop date. If AE#1 is confirmed with a stop date. Review if medication should have a corresponding stop date. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 11:43:07
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty; reason for change Data Entry Error	gail lavine (b) (4) (b) (4)	08 Feb 2021 13:02:58
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 18:34:55
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 17:05:16

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 16:02:02
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 17:05:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:07:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:07:54
Data point term sent to Coder	System	30 Oct 2020 17:07:08
User entered 'HYDROCODONE'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'FIBROMYALGIA'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User closed query 'Per DM CLR: Please review dose as there are two doses indicated. However, medication is a single dose drug. Either update Medication or update dose. Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 09:10:43
Query 'Per DM CLR: Please review dose as there are two doses indicated. However, medication is a single dose drug. Either update Medication or update dose. Update accordingly. ' answered with 'corrected' (Site from DM).	gail lavine (b) (4) (b) (4)	08 Feb 2021 13:05:53
User entered '5' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	08 Feb 2021 13:05:41
User opened query 'Per DM CLR: Please review dose as there are two doses indicated. However, medication is a single dose drug. Either update Medication or update dose. Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 11:39:36
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:24:55
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 14:31:34
User entered '5/325' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 14:31:28
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 08:16:02
User entered '325'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'as needed (PRN)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'UN UNK 2005'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:06:52

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 10:58:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 10:58:14
Data point term sent to Coder	System	30 Oct 2020 17:09:09
User entered 'LEVOTHYROXINE'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'HYPOPARATHYROIDISM'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '100'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'ug (ug)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'once daily (QD)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'UN UNK 2015'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 17:08:49

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 10:58:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 10:58:14
Data point term sent to Coder	System	30 Oct 2020 17:13:12
Data point term sent to Coder	System	30 Oct 2020 17:12:10
Data point term sent to Coder	System	30 Oct 2020 17:10:09
User entered 'LIOTHYRONINE'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'HYPOPARATHYROIDISM'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '25'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

FDA-CBER-2022-1614-3554317

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'ug (ug)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 16:02:02
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'other (OTHER)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:12:10
User entered 'once daily (QD)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	30 Oct 2020 17:12:47
User entered 'MON/WED/FRI' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:12:47
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	30 Oct 2020 17:12:10
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	30 Oct 2020 17:13:08
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	30 Oct 2020 17:12:10
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:13:08
User entered 'MON/WED/FRI' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:12:10
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'UN UNK 2010'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:09:56

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:12:10
User entered '1'	System	30 Oct 2020 17:09:56

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:12:10
User entered '1'	System	30 Oct 2020 17:09:56

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:12:10
User entered '804 (804)'	System	30 Oct 2020 17:09:56

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:12:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:12:54
Data point term sent to Coder	System	30 Oct 2020 17:12:11
User entered 'MELOXICAM'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'FIBROMYALGIA'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '7.5'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'twice daily (BID)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

FDA-CBER-2022-1614-3554338

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'UN UNK 2000'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:11:27

FDA-CBER-2022-1614-3554346

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 17:11:27

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: NORTRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 01:03:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 01:03:10
Data point term sent to Coder	System	30 Oct 2020 17:17:14
User entered 'NORTRIPTYLINE'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User closed query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 12:28:19
Query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 13:25:20
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 13:25:08
User opened query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 08:16:36
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

FDA-CBER-2022-1614-3554351

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'MUSCLE SPASMS'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '25'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'once daily (QD)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'UN UNK 2005'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 17:16:17

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE, PRODUCTSYNONYM: ORACEA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:22:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:22:05
Data point term sent to Coder	System	30 Oct 2020 17:21:20
User entered 'ORACEA'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'ROSACEA'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '40'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'as needed (PRN)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'UN UNK 2005'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:20:58

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:23:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:23:03
Data point term sent to Coder	System	30 Oct 2020 17:22:21
User entered 'TIZANIDINE'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User closed query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 12:28:32
Query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 13:30:09
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 13:30:02
User opened query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 08:16:44
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'MUSCLE SPASMS'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '4'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'as needed (PRN)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'UN UNK 2005'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:22:08

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:22:08

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:23:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 17:23:54
Data point term sent to Coder	System	30 Oct 2020 17:23:22
User entered 'TRAMADOL'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

FDA-CBER-2022-1614-3554404

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'FIBROMYALGIA'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '100'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'as needed (PRN)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'UN UNK 2010'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 17:23:16

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 00:45:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 00:45:05
Data point term sent to Coder	System	30 Oct 2020 17:27:28
User entered 'VENLAFAXINE'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'DEPRESSION OVER FIBROMYALGIA'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '37.5'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'twice daily (BID)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'UN UNK 2000'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

FDA-CBER-2022-1614-3554434

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 17:27:26

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 14:04:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 14:04:04
Data point term sent to Coder	System	18 Nov 2020 14:02:44
User entered 'MULTIVITAMIN'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'SUPPLEMENT'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '1'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'tablet (TABLET)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

FDA-CBER-2022-1614-3554444

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'once daily (QD)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '1'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 14:02:13

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 14:02:13

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 14:02:13

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, PRODUCT: OMEGA-3 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 14:20:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 14:20:04
Data point term sent to Coder	System	18 Nov 2020 14:04:45
Data point term sent to Coder	System	18 Nov 2020 14:03:45
User entered 'OMEGA 3'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 14:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 14:04:04
User entered 'SUPPLEMENT' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 14:03:15
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '1200'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'mg (mg)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'once daily (QD)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '1'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 14:03:15

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 12:48:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 12:48:28
Data point term sent to Coder	System	11 Dec 2020 12:47:02
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	11 Dec 2020 12:46:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 14:07:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 14:07:05
Data point term sent to Coder	System	18 Nov 2020 14:05:46
User entered 'INFLUENZA VACCINE'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User closed query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event/MH record that match with this condition? Kindly update appropriately.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:25:33
Query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event/MH record that match with this condition? Kindly update appropriately.' answered with 'THIS IS NOT AN AE OR A MEDICAL CONDITION. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	11 Dec 2020 12:48:18
User entered 'INFLUENZA' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	11 Dec 2020 12:46:36
User opened query 'Per CDM: Please review Indication and note that there is no corresponding Adverse Event/MH record that match with this condition? Kindly update appropriately.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 16:40:14
User entered 'SEASONAL INFLUENZA'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '1'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Other (OTHER)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:25:34
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	01 Dec 2020 18:03:30
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	01 Dec 2020 18:03:20
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 10:35:02
User entered 'DOSAGE NOT KNOWN'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

FDA-CBER-2022-1614-3554481

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'once (ONCE)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Intramuscular (INTRAMUSCULAR)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '24 Sep 2020'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '24 Sep 2020'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User entered empty.	System	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User entered empty.	System	18 Nov 2020 14:05:34

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:12:18
User entered empty.	System	18 Nov 2020 14:05:34

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN SULFATE;GLUCOSAMINE SULFATE;METHYLSULFONYLMETHANE, PRODUCTSYNONYM: GLUCOSAMINE CHONDROITIN & MSM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:44:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:44:16
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
Data point term sent to Coder	System	17 Feb 2021 16:26:52
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	17 Feb 2021 16:26:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN SULFATE;GLUCOSAMINE SULFATE POTASSIUM CHLORIDE;METHYLSULFONYLMETHANE, PRODUCTSYNONYM: GLUCOSAMINE AND CHONDROITIN WITH MSM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:42:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 22:42:29
Data point term sent to Coder	System	04 Feb 2021 18:33:40
User entered 'Glucosamine Chondroitin with MSM'	(b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	08 Feb 2021 13:06:46
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:15:35
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'THERE IS NOT AN UNDERLYING CONDITION. THIS IS FOR PROPHYLAXIS' (Site from DM).	Albert Garcia (b) (4) (b) (4)	17 Feb 2021 16:26:46
User entered 'CARTILAGE SUPPORT - PROPHYLAXIS.' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	17 Feb 2021 16:26:12
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:55:12
User entered 'Cartilage Support'	(b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of capsules. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:15:43
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of capsules. Please verify the dose and unit, and update as appropriate. ' answered with 'THIS DOSE CANNOT BE CONFIRMED. PLEASE REMOVE QUERY' (Site from DM).	Albert Garcia (b) (4) (b) (4)	17 Feb 2021 16:27:17
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of capsules. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:55:21
User entered '1'	(b) (4), (b) (6)	04 Feb 2021 18:33:35

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:48:03
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 18:33:35

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:48:03
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:48:03
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:48:03
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:48:03
	(b) (4)	
User entered '03 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	(b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:48:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:48:03
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '3'	System	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 18:33:35

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 18:33:35

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 18:37:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 18:37:50
Data point term sent to Coder	System	04 Feb 2021 18:36:44
User entered 'LOSARTAN'	(b) (4), (b) (6)	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'HYPERTENSION'	(b) (4), (b) (6)	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '50'	(b) (4), (b) (6)	04 Feb 2021 18:35:53

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 18:35:53

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:48:03
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 09:38:26
User entered '06 Jan 2021' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	20 Feb 2021 17:34:58
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'updated' (Site from DM).	Diana Toney (b) (4) (b) (4)	20 Feb 2021 17:32:22
User entered '02 Oct 2020' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	20 Feb 2021 17:32:11
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:56:12
User entered '06 Jan 2021'	(b) (4), (b) (6)	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered '0'	(b) (4), (b) (6)	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:48:03
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 18:35:53

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 16:02:02
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 18:35:53

US3222004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:02:02

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:00
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	24 Nov 2020 20:34:25
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	24 Nov 2020 20:34:25
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:58:55
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	09 Oct 2020 13:16:08

US3222004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:02:02

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '01 Oct 2020'	douglas winter (b) (4) (b) (4)	24 Nov 2020 20:42:10

US3222004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:02:02

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '2D ECHO'	douglas winter (b) (4) (b) (4)	24 Nov 2020 20:42:10

US3222004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Adverse Event (AE)'	douglas winter (b) (4) (b) (4)	24 Nov 2020 20:42:10

US3222004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:02:02

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	douglas winter (b) (4) (b) (4)	24 Nov 2020 20:42:10

US3222004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:02:02

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '01 Oct 2020'	douglas winter (b) (4) (b) (4)	24 Nov 2020 20:42:55

US3222004
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 16:02:02

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:11:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'STRESS TEST'	douglas winter (b) (4) (b) (4)	24 Nov 2020 20:42:55

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:11:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Adverse Event (AE)'	douglas winter (b) (4) (b) (4)	24 Nov 2020 20:42:55

US3222004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:02:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:11:20
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	douglas winter (b) (4) (b) (4)	24 Nov 2020 20:42:55

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:11:24
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '01 Oct 2020'	Alicia Cevera (b) (4) (b) (4)	01 Dec 2020 20:58:13

FDA-CBER-2022-1614-3554539

US3222004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:02:02

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) / (b) (4), (b) (6)	01 May 2021 07:11:24
User signature succeeded.	Bruce Rankin (b) (4) / (b) (4)	16 Feb 2021 16:25:57
User entered 'BLOOD WORK FOR TROPONINS'	Alicia Cevera (b) (4) / (b) (4)	01 Dec 2020 20:58:13

US3222004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:02:02

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:11:24
User closed query 'Per CDM - RQ: Response noted "Updated". However update is not obvious please provide location of update such as log line number.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 04:04:37
Query 'Per CDM - RQ: Response noted "Updated". However update is not obvious please provide location of update such as log line number.' answered with 'PLEASE REVIEW THE CORRESPONDING AE AND NOTE THAT CONCOMITANT PROCEDURE IS CHECKED YES. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	05 Mar 2021 18:58:08
User opened query 'Per CDM - RQ: Response noted "Updated". However update is not obvious please provide location of update such as log line number.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:15:20
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:15:20
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'updated' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	04 Mar 2021 14:02:40
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:17:18
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Adverse Event (AE)'	Alicia Cevera (b) (4) (b) (4)	01 Dec 2020 20:58:13

US3222004

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:02:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 07:11:24
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered empty.	Alicia Cevera (b) (4) (b) (4)	01 Dec 2020 20:58:13

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'USA-US104-2020-MRNA-1273-P301000011'	System	12 Oct 2020 14:09:45

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554546

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554547

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554548

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554550

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
User signature succeeded.	(b) (4), (b) (6) Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:05:53
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Teresa'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Lisa'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:34
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Tracy'	System	12 Oct 2020 14:09:45

US3222004

Folder: SAE USA-US104-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Investigator's Last Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
User signature succeeded.	(b) (4), (b) (6) Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:05:53
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Becker'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Holloway'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Kowalski'	System	12 Oct 2020 14:09:45

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:23:41

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Houston'	System	02 Dec 2020 15:23:41

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:05:53
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered empty.	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered 'TX'	System	02 Dec 2020 15:23:41

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered '77081'	(b) (4) System	02 Dec 2020 15:23:41

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:53:28
User entered 'US'	System	12 Oct 2020 14:10:07

Audit	User	Time (GMT)
User entered '6'	System	09 Mar 2021 14:21:11
User entered '5'	System	05 Mar 2021 16:30:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '4'	System	02 Dec 2020 15:23:41
User entered '3'	System	30 Oct 2020 20:53:44
User entered '2'	System	16 Oct 2020 18:53:43
User entered '1'	System	12 Oct 2020 14:10:07

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'USA-US104-2020-MRNA-1273-P301000011'	System	12 Oct 2020 14:09:45

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554561

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

Investigator's First Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:05:53
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Teresa'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Lisa'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:34
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Tracy'	System	12 Oct 2020 14:09:45

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:05:53
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Becker'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Holloway'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Kowalski'	System	12 Oct 2020 14:09:45

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:23:41

FDA-CBER-2022-1614-3554569

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Houston'	System	02 Dec 2020 15:23:41

FDA-CBER-2022-1614-3554570

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:05:53
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered empty.	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered 'TX'	System	02 Dec 2020 15:23:41

FDA-CBER-2022-1614-3554571

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '77081'	System	02 Dec 2020 15:23:41

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:53:28
User entered 'US'	System	12 Oct 2020 14:10:07

FDA-CBER-2022-1614-3554573

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	09 Mar 2021 14:21:11
User entered '5'	System	05 Mar 2021 16:30:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '4'	System	02 Dec 2020 15:23:41
User entered '3'	System	30 Oct 2020 20:53:44
User entered '2'	System	16 Oct 2020 18:53:43
User entered '1'	System	12 Oct 2020 14:10:07

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 16:02:02
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
User entered '12/Oct/2020 10:10'	System	12 Oct 2020 14:10:07

US3222004

Folder: SAE USA-US104-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:02:02

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.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:53:28
User entered '1'	(b) (4), (b) (6)	12 Oct 2020 14:10:07

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'USA-US104-2020-MRNA-1273-P301000011'	System	12 Oct 2020 14:09:45

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554580

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554581

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554582

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554583

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554584

Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02

Investigator's First Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
User signature succeeded.	(b) (4), (b) (6) Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:05:53
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Teresa'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Lisa'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:34
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Tracy'	System	12 Oct 2020 14:09:45

Investigator's Last Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:05:53
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Becker'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Holloway'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Kowalski'	System	12 Oct 2020 14:09:45

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:23:41

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered 'Houston'	System	02 Dec 2020 15:23:41

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:05:53
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered empty.	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered 'TX'	System	02 Dec 2020 15:23:41

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered '77081'	System	02 Dec 2020 15:23:41

FDA-CBER-2022-1614-3554590

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:53:28
User entered 'US'	System	12 Oct 2020 14:10:07

FDA-CBER-2022-1614-3554591

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	09 Mar 2021 14:21:11
User entered '5'	System	05 Mar 2021 16:30:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '4'	System	02 Dec 2020 15:23:41
User entered '3'	System	30 Oct 2020 20:53:44
User entered '2'	System	16 Oct 2020 18:53:43
User entered '1'	System	12 Oct 2020 14:10:07

FDA-CBER-2022-1614-3554592

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 16:02:02
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
User entered '16/Oct/2020 18:53'	System	16 Oct 2020 18:53:43

US3222004

Folder: SAE USA-US104-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:02:02

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.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:53:55
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 18:53:43

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'USA-US104-2020-MRNA-1273-P301000011'	System	12 Oct 2020 14:09:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554596

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554597

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554598

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554600

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554601

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02

Investigator's First Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
User signature succeeded.	(b) (4), (b) (6) Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:05:53
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Teresa'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Lisa'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:34
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Tracy'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554603

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02

Investigator's Last Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:05:53
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Becker'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Holloway'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Kowalski'	System	12 Oct 2020 14:09:45

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:23:41

FDA-CBER-2022-1614-3554605

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Houston'	System	02 Dec 2020 15:23:41

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:05:53
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered empty.	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered 'TX'	System	02 Dec 2020 15:23:41

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered '77081'	(b) (4) System	02 Dec 2020 15:23:41

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:53:28
User entered 'US'	System	12 Oct 2020 14:10:07

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	09 Mar 2021 14:21:11
User entered '5'	System	05 Mar 2021 16:30:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '4'	System	02 Dec 2020 15:23:41
User entered '3'	System	30 Oct 2020 20:53:44
User entered '2'	System	16 Oct 2020 18:53:43
User entered '1'	System	12 Oct 2020 14:10:07

US3222004

Folder: SAE USA-US104-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
User entered '30/Oct/2020 16:53'	System	30 Oct 2020 20:53:44

US3222004

Folder: SAE USA-US104-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:02:02

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.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 15:23:33
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 20:53:44

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'USA-US104-2020-MRNA-1273-P301000011'	System	12 Oct 2020 14:09:45

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554618

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554619

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
User signature succeeded.	(b) (4), (b) (6) Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:05:53
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Teresa'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Lisa'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:34
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Tracy'	System	12 Oct 2020 14:09:45

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
User signature succeeded.	(b) (4), (b) (6) Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:05:53
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Becker'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Holloway'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Kowalski'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554622

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:23:41

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Houston'	System	02 Dec 2020 15:23:41

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Mar 2021 14:21:00
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:05:53
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered empty.	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'TX'	System	02 Dec 2020 15:23:41

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '77081'	System	02 Dec 2020 15:23:41

FDA-CBER-2022-1614-3554626

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:53:28
User entered 'US'	System	12 Oct 2020 14:10:07

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	09 Mar 2021 14:21:11
User entered '5'	System	05 Mar 2021 16:30:56
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered '4'	System	02 Dec 2020 15:23:41
User entered '3'	System	30 Oct 2020 20:53:44
User entered '2'	System	16 Oct 2020 18:53:43
User entered '1'	System	12 Oct 2020 14:10:07

Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 16:02:02
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '02/Dec/2020 15:23'	System	02 Dec 2020 15:23:41

US3222004

Folder: SAE USA-US104-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:02:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:23:41

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'USA-US104-2020-MRNA-1273-P301000011'	System	12 Oct 2020 14:09:45

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554633

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554634

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554636

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554637

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Investigator's First Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:05:53
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Teresa'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Lisa'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:34
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Tracy'	System	12 Oct 2020 14:09:45

Investigator's Last Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:05:53
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Becker'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Holloway'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Kowalski'	System	12 Oct 2020 14:09:45

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:23:41

FDA-CBER-2022-1614-3554641

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Houston'	System	02 Dec 2020 15:23:41

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Mar 2021 14:21:00
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:05:53
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered empty.	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'TX'	System	02 Dec 2020 15:23:41

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered '77081'	System	02 Dec 2020 15:23:41

FDA-CBER-2022-1614-3554644

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:53:28
User entered 'US'	System	12 Oct 2020 14:10:07

FDA-CBER-2022-1614-3554645

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	09 Mar 2021 14:21:11
User entered '5'	System	05 Mar 2021 16:30:56
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered '4'	System	02 Dec 2020 15:23:41
User entered '3'	System	30 Oct 2020 20:53:44
User entered '2'	System	16 Oct 2020 18:53:43
User entered '1'	System	12 Oct 2020 14:10:07

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 16:02:02
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:05:53
User entered '05/Mar/2021 11:30'	System	05 Mar 2021 16:30:56

US3222004

Folder: SAE USA-US104-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:02:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
User signature succeeded.	(b) (4), (b) (6) Vicki Miller (b) (4)	05 Mar 2021 21:05:53
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:30:56

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'USA-US104-2020-MRNA-1273-P301000011'	System	12 Oct 2020 14:09:45

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554652

Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Yes (Y)'	System	12 Oct 2020 14:09:45

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554654

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'No (N)'	System	12 Oct 2020 14:09:45

Investigator's First Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
User signature succeeded.	(b) (4), (b) (6) Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:05:53
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Teresa'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Lisa'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:34
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Tracy'	System	12 Oct 2020 14:09:45

FDA-CBER-2022-1614-3554657

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Investigator's Last Name

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
User signature succeeded.	(b) (4), (b) (6) Vicki Miller (b) (4) (b) (4)	05 Mar 2021 21:05:53
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered 'Becker'	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
Un-reviewed for Safety.	System	02 Dec 2020 15:23:41
User entered 'Holloway'	System	02 Dec 2020 15:23:41
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 15:55:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:09:59
User entered 'Kowalski'	System	12 Oct 2020 14:09:45

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '6550 Mapleridge Street'	System	02 Dec 2020 15:23:41

FDA-CBER-2022-1614-3554659

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered 'Houston'	System	02 Dec 2020 15:23:41

FDA-CBER-2022-1614-3554660

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:21:00
	(b) (4), (b) (6)	
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:05:53
	(b) (4)	
Un-reviewed for Safety.	System	05 Mar 2021 16:30:56
Signature has been broken.	System	05 Mar 2021 16:30:56
User entered empty.	System	05 Mar 2021 16:30:56
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
User entered 'TX'	System	02 Dec 2020 15:23:41

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:30:37
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
User entered '77081'	(b) (4) System	02 Dec 2020 15:23:41

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form
Generated On: 09 Jun 2021 16:02:02
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 16:25:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 20:42:21
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:53:28
User entered 'US'	System	12 Oct 2020 14:10:07

US3222004

Folder: SAE USA-US104-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '6'	System	09 Mar 2021 14:21:11
User entered '5'	System	05 Mar 2021 16:30:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	16 Feb 2021 16:25:57
User entered '4'	System	02 Dec 2020 15:23:41
User entered '3'	System	30 Oct 2020 20:53:44
User entered '2'	System	16 Oct 2020 18:53:43
User entered '1'	System	12 Oct 2020 14:10:07

US3222004
Folder: SAE USA-US104-2020-MRNA-1273-P301000011
Form: Safety Report Form (6)
Generated On: 09 Jun 2021 16:02:02
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
User entered '09/Mar/2021 09:21'	System	09 Mar 2021 14:21:11

US3222004

Folder: SAE USA-US104-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:02:02

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.	Bruce Rankin (b) (4) (b) (4)	25 Mar 2021 17:10:02
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Mar 2021 14:21:17
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	09 Mar 2021 14:21:11