US3742137 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:34:30

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US3742137
Form: Participant Creation
Data signed: (b) (4) **23 Feb 2021 17:18:22**
Generated On: 10 Jun 2021 09:34:30

Participant ID	US3742137

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-3118837

US3742137
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 17:14:59**
Generated On: 10 Jun 2021 09:34:30

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

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US3742137
Folder: Screening
Form: Demographics
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Date of Birth (MMM yyyy)	(b) (6) 1980
Age	40
Age Units	YEARS
Age (Derived)	40
Sex	Female ■ Male ☐
Ethnicity	Hispanic or Latino ■ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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US3742137
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Date of Informed Consent *(dd MMM yyyy)*	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ☐ Amendment 3 ■ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

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US3742137
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Did the participant meet all eligibility criteria?	Yes ■ No ☐

US3742137
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **15 Feb 2021 17:14:59**
Generated On: 10 Jun 2021 09:34:30

Were any significant conditions reported?	Yes ■ No ☐

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US3742137
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	04 OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	05 OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

US3742137
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	MENOMETRORRHAGIA
Start date (dd MMM yyyy)	04 OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	05 OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

US3742137
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	ABDOMINAL LAPAROSCOPY
Start date (dd MMM yyyy)	UN JAN 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

FDA-CBER-2022-1614-3118845

US3742137
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN JAN 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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US3742137
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	BUNIONECTOMY
Start date (dd MMM yyyy)	01 JUN 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	01 JUN 2015
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JUN 2015
Stop Year (derived)	2015

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US3742137
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	ANXIETY
Start date (dd MMM yyyy)	14 DEC 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)	DEC 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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US3742137
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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US3742137
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

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

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US3742137
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	INDIGESTION
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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US3742137
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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US3742137
Folder: Screening
Form: Medical History (12)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	ALLERGY TO CONTRAST DYE (SNEEZING)
Start date (dd MMM yyyy)	22 NOV 2013
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)	NOV 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3742137
Folder: Screening
Form: Medical History (13)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	ALLERGY TO AVOCODO
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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US3742137
Folder: Screening
Form: Medical History (14)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	GENERALIZED PAIN
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3118855

US3742137
Folder: Screening
Form: Medical History (15)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

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

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US3742137
Folder: Screening
Form: Medical History (16)
Data signed: (b) (4) **25 Mar 2021 17:50:21**
Generated On: 10 Jun 2021 09:34:30

Condition	MIGRAINES HEADACHES
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3118857

US3742137
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 17:14:59**
Generated On: 10 Jun 2021 09:34:30

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	28 AUG 2020
Time of assessment *(00:00-23:59)*	11:37 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:37
Height *(xxx.x)*	64.0 in
Weight *(xxx.x)*	170 lb
BMI *(xxx.x)*	29.24145 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)	

US3742137
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 17:14:59**
Generated On: 10 Jun 2021 09:34:30

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	28 AUG 2020

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

FDA-CBER-2022-1614-3118859

US3742137
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **15 Feb 2021 17:14:58**
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Date of assessment *(dd MMM yyyy)*	28 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)*	4 OCT 2019
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

FDA-CBER-2022-1614-3118860

US3742137
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **15 Feb 2021 17:14:59**
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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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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

FDA-CBER-2022-1614-3118862

US3742137
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

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US3742137
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **15 Feb 2021 17:14:59**
Generated On: 10 Jun 2021 09:34:30

What was the date of randomization? *(dd MMM yyyy)*	28 AUG 2020
What was the participant's randomization number?	109479
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ■ >=18 and <65 years and at risk ☐ >=65 years ☐

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ☐ No ■
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ☐ No ■
Severe obesity (body mass index > or = 40kg/m2	Yes ☐ No ■
Diabetes (Type I, Type 2, or gestational)	Yes ☐ No ■
Liver Disease	Yes ☐ No ■
Human Immunodeficiency Virus (HIV) infection	Yes ☐ No ■

FDA-CBER-2022-1614-3118864

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Height	ND - Not Done
Weight	ND - Not Done

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US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

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)*	28 AUG 2020
Time of assessment *(00:00-23:59)*	11:37 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:37
Temperature *(xxx.x)*	098.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	086 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	085 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3118866

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

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)*	28 AUG 2020
Time of assessment *(00:00-23:59)*	14:12 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 14:12
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	FOREHEAD
Pulse *(xxx)*	086 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	078 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3118867

US3742137
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 17:14:59**
Generated On: 10 Jun 2021 09:34:30

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.

FDA-CBER-2022-1614-3118868

US3742137
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 17:14:59**
Generated On: 10 Jun 2021 09:34:30

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)*	28 AUG 2020
What was the treatment time? *(00:00-23:59)*	13:41 (24 HR)
Treatment Date and Time (derived)	28 AUG 2020 13:41
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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US3742137
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 17:14:59**
Generated On: 10 Jun 2021 09:34:30

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	28 AUG 2020
Collection time *(00:00-23:59)*	12:39 (24 HR)
Collection date and time (derived)	28 AUG 2020 12:39

FDA-CBER-2022-1614-3118870

US3742137
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 17:14:59**
Generated On: 10 Jun 2021 09:34:30

Collection date *(dd MMM yyyy)*			28 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:43	28 AUG 2020 12:43
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-3118871

US3742137
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:14:59**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

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US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	28 AUG 2020 14:15
PC Open Date & Time	28 AUG 2020 14:01
PC Close Date & Time	28 AUG 2020 16:31

FDA-CBER-2022-1614-3118873

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**	99.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	28 AUG 2020 21:22
PC Open Date & Time	28 AUG 2020 17:26
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-3118874

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30

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**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	29 AUG 2020 13:41
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-3118875

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30

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	30 AUG 2020 13:23
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-3118876

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	99.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	31 AUG 2020 18:25
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30

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 ■
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	01 SEP 2020 18:37
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30

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**	99.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 SEP 2020 17:01
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-3118879

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30

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**	99.3 °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	03 SEP 2020 20:21
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30

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	28 AUG 2020 14:16
PC Open Date & Time	28 AUG 2020 14:01
PC Close Date & Time	28 AUG 2020 16:31

FDA-CBER-2022-1614-3118881

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30

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	28 AUG 2020 21:24
PC Open Date & Time	28 AUG 2020 17:26
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-3118882

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	1
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	29 AUG 2020 13:42
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-3118883

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30

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	30 AUG 2020 13:24
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30

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	31 AUG 2020 18:25
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-3118885

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30

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	01 SEP 2020 18:37
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30

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	02 SEP 2020 17:02
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30

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	03 SEP 2020 20:21
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-3118888

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-2022-1614-3118889

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	28 AUG 2020 14:16
PC Open Date & Time	28 AUG 2020 14:01
PC Close Date & Time	28 AUG 2020 16:31

FDA-CBER-2022-1614-3118890

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 ☐

FDA-CBER-2022-1614-3118891

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	28 AUG 2020 21:24
PC Open Date & Time	28 AUG 2020 17:26
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-3118892

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30

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 ■

FDA-CBER-2022-1614-3118893

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30

	Yes ☐
PC Time stamp	29 AUG 2020 13:43
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30

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 ■

FDA-CBER-2022-1614-3118895

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30

	Yes ☐
PC Time stamp	30 AUG 2020 13:24
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30

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-2022-1614-3118897

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30

	Yes ☐
PC Time stamp	31 AUG 2020 18:25
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

TIMEPOINT	DAY 5
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3118899

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30

	Yes ☐
PC Time stamp	01 SEP 2020 18:37
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 6
HEADACHE	None ☐
	No interference with activity ■
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ■
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3118901

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30

	Yes ☐
PC Time stamp	02 SEP 2020 17:02
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30

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-2022-1614-3118903

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30

	Yes ☐
PC Time stamp	03 SEP 2020 20:22
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3742137
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	4 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-3118905

US3742137
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3118906

US3742137
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	11 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3118907

US3742137
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3118908

US3742137
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3118909

US3742137
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3118910

US3742137
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-3118911

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	25 SEP 2020
Time of assessment *(00:00-23:59)*	11:10 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 11:10
Temperature *(xxx.x)*	098.4 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	085 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	083 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3118912

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	25 SEP 2020
Time of assessment *(00:00-23:59)*	12:34 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 12:34
Temperature *(xxx.x)*	098.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	081 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	082 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3118913

US3742137
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	25 SEP 2020

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

FDA-CBER-2022-1614-3118914

US3742137
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

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)*	25 SEP 2020
What was the treatment time? *(00:00-23:59)*	12:04 (24 HR)
Treatment Date and Time (derived)	25 SEP 2020 12:04
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

FDA-CBER-2022-1614-3118915

US3742137
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	25 SEP 2020
Collection time *(00:00-23:59)*	11:26 (24 HR)
Collection date and time (derived)	25 SEP 2020 11:26

US3742137
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Collection date *(dd MMM yyyy)*			25 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:25	25 SEP 2020 11:25
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-3118917

US3742137
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3118918

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	25 SEP 2020 12:36
PC Open Date & Time	25 SEP 2020 12:24
PC Close Date & Time	25 SEP 2020 14:54

FDA-CBER-2022-1614-3118919

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**	99.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	25 SEP 2020 19:21
PC Open Date & Time	25 SEP 2020 15:49
PC Close Date & Time	26 SEP 2020 11:59

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30

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**	102.0 °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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	26 SEP 2020 19:35
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-3118921

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30

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**	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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	27 SEP 2020 18:41
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-3118922

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	99.2 °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	28 SEP 2020 21:07
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

FDA-CBER-2022-1614-3118923

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30

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.

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	29 SEP 2020 22:40
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-3118924

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 6

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	30 SEP 2020 22:53
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 7

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

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

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Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
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You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	99.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	01 OCT 2020 18:03
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30

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	25 SEP 2020 12:37
PC Open Date & Time	25 SEP 2020 12:24
PC Close Date & Time	25 SEP 2020 14:54

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30

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	25 SEP 2020 19:22
PC Open Date & Time	25 SEP 2020 15:49
PC Close Date & Time	26 SEP 2020 11:59

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	3
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.	2
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	26 SEP 2020 19:35
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	115
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.	110
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	27 SEP 2020 18:42
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	120
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.	120
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	28 SEP 2020 21:07
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

FDA-CBER-2022-1614-3118931

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30

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.	70
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.	70
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	29 SEP 2020 22:41
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-3118932

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30

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	30 SEP 2020 22:53
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30

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	01 OCT 2020 18:04
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

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-2022-1614-3118935

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	25 SEP 2020 12:38
PC Open Date & Time	25 SEP 2020 12:24
PC Close Date & Time	25 SEP 2020 14:54

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 ☐

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	25 SEP 2020 19:23
PC Open Date & Time	25 SEP 2020 15:49
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-3118938

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30

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 ■

FDA-CBER-2022-1614-3118939

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30

	Yes ☐
PC Time stamp	26 SEP 2020 19:36
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30

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 ■

FDA-CBER-2022-1614-3118941

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30

	Yes ☐
PC Time stamp	27 SEP 2020 18:42
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-3118942

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30

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-2022-1614-3118943

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30

	Yes ☐
PC Time stamp	28 SEP 2020 21:07
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

TIMEPOINT	DAY 5
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ■
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3118945

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30

	Yes ☐
PC Time stamp	29 SEP 2020 22:41
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 6
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3118947

	Yes ☐
PC Time stamp	30 SEP 2020 22:54
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30

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-2022-1614-3118949

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30

	Yes ☐
PC Time stamp	01 OCT 2020 18:04
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3742137
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **HEADACHE**	None ☐ No interference with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	02 OCT 2020 21:15
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-3118951

US3742137
Folder: Diary Dose 2 (1)
Form: Headache_Day(9)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 9
Select one response below to indicate the intensity of your **HEADACHE**	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	03 OCT 2020 18:56
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-3118952

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	02 OCT 2020 21:15
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-3118953

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 9
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	03 OCT 2020 18:56
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-3118954

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(10)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 10
Select one response below to indicate the intensity of your **FATIGUE**	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	04 OCT 2020 16:28
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-3118955

US3742137
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	02 OCT 2020 21:15
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-3118956

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	02 OCT 2020 21:15
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	03 OCT 2020 18:56
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-3118958

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	04 OCT 2020 16:28
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-3118959

US3742137
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-3118960

US3742137
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3118961

US3742137
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3118962

US3742137
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3118963

US3742137
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-3118964

US3742137
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:14:58**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3118965

US3742137
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-3118966

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

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)	

US3742137
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	22 OCT 2020

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

FDA-CBER-2022-1614-3118968

US3742137
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	22 OCT 2020
Collection time *(00:00-23:59)*	10:17 (24 HR)
Collection date and time (derived)	22 OCT 2020 10:17

FDA-CBER-2022-1614-3118969

US3742137
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:15:13**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3118970

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 02:46:39
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

FDA-CBER-2022-1614-3118971

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 18:58:37
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 14:24:47
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 NOV 2020 11:50:46
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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	01 DEC 2020 14:55:05
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

FDA-CBER-2022-1614-3118975

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 15:10:44
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

FDA-CBER-2022-1614-3118976

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	13 DEC 2020 23:12:48
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

FDA-CBER-2022-1614-3118977

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 10:55:12
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 09:40:51
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ■
Please contact your study clinic immediately. Click below to confirm that you have read this 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	03 JAN 2021 09:47:39
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

FDA-CBER-2022-1614-3118980

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	11 JAN 2021 16:13:15
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	17 JAN 2021 09:57:43
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

FDA-CBER-2022-1614-3118982

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ■
Please contact your study clinic immediately. Click below to confirm that you have read this 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	24 JAN 2021 20:23:47
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

FDA-CBER-2022-1614-3118983

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	31 JAN 2021 18:49:06
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 15:27:51
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

FDA-CBER-2022-1614-3118985

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	14 FEB 2021 17:53:29
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

FDA-CBER-2022-1614-3118986

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	21 FEB 2021 11:21:06
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

FDA-CBER-2022-1614-3118987

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	28 FEB 2021 10:05:54
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

FDA-CBER-2022-1614-3118988

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	07 MAR 2021 14:53:51
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	14 MAR 2021 16:25:05
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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 ■
Please contact your study clinic immediately. Click below to confirm that you have read this 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	22 MAR 2021 10:37:35
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

FDA-CBER-2022-1614-3118991

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	30 MAR 2021 12:00:26
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 APR 2021 11:38:15
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	11 APR 2021 13:51:17
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

FDA-CBER-2022-1614-3118994

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	19 APR 2021 08:13:53
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	25 APR 2021 20:51:47
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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	02 MAY 2021 08:52:00
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 MAY 2021 00:01
Patient Cloud Close Date & Time	20 MAY 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):	
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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	23 MAY 2021 00:01
Patient Cloud Close Date & Time	27 MAY 2021 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 MAY 2021 00:01
Patient Cloud Close Date & Time	03 JUN 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 JUN 2021 00:01
Patient Cloud Close Date & Time	10 JUN 2021 23:59

FDA-CBER-2022-1614-3119007

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	04 JUL 2021 00:01
Patient Cloud Close Date & Time	08 JUL 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	01 AUG 2021 00:01
Patient Cloud Close Date & Time	05 AUG 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	08 AUG 2021 00:01
Patient Cloud Close Date & Time	12 AUG 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	15 AUG 2021 00:01
Patient Cloud Close Date & Time	19 AUG 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 AUG 2021 00:01
Patient Cloud Close Date & Time	02 SEP 2021 23:59

FDA-CBER-2022-1614-3119031

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	19 SEP 2021 00:01
Patient Cloud Close Date & Time	23 SEP 2021 23:59

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

FDA-CBER-2022-1614-3119047

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

FDA-CBER-2022-1614-3119051

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

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 NOV 2021 00:01
Patient Cloud Close Date & Time	02 DEC 2021 23:59

FDA-CBER-2022-1614-3119057

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

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 ≥ 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 ☐

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

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 ≥ 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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	03 MAR 2022 23:59

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	31 MAR 2022 23:59

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

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

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

FDA-CBER-2022-1614-3119099

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

FDA-CBER-2022-1614-3119109

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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-2022-1614-3119110

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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-2022-1614-3119116

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

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

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 ≥ 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 ☐

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

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

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

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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):	
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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

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 ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

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 ≥ 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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

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

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ≥ 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 ☐

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

FDA-CBER-2022-1614-3119151

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	03 NOV 2022 23:59

US3742137
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 10 Jun 2021 09:34:30

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 10:06:17

FDA-CBER-2022-1614-3119154

US3742137
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-3119155

US3742137
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3119156

US3742137
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-3119157

US3742137
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3119158

US3742137
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	21 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-3119159

US3742137
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3119160

US3742137
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3119161

US3742137
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3119162

US3742137
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT4

FDA-CBER-2022-1614-3119163

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

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)	

US3742137
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

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.

US3742137
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	23 MAR 2021
Collection time *(00:00-23:59)*	13:12 (24 HR)
Collection date and time (derived)	23 MAR 2021 13:12

US3742137
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3119167

US3742137
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **23 Apr 2021 17:54:08**
Generated On: 10 Jun 2021 09:34:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 APR 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-3119168

US3742137
Folder: Safety Call Day 239 (1)
Form: Continuing
Data signed: (b) (4) **23 Apr 2021 17:54:08**
Generated On: 10 Jun 2021 09:34:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-3119169

US3742137
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30

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	

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID-19 Contact
Data signed: (b) (4) **23 Feb 2021 17:18:23**
Generated On: 10 Jun 2021 09:34:30

Date of Contact	30 NOV 2020
Time of Contact	13:05
Date and Time of Contact (derived)	30 NOV 2020 13:05
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 ☐

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Symptom Day

- [x] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
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- [ ] Day 7
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- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
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- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-3119173

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	26 NOV 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	100.9 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

	Not Done ☐
Fatigue	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

FDA-CBER-2022-1614-3119175

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-3119176

Symptom Day

- [ ] Day 1
- [x] Day 2
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- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-3119177

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	27 NOV 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	100.9 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

	Not Done ☐
Fatigue	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [x] Day 3
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- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-3119181

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	28 NOV 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	100.0 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

	Not Done ☐
Fatigue	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-3119184

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [x] Day 4
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- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-3119185

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	29 NOV 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	99.8 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

	Not Done ☐
Fatigue	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [x] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
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- [ ] Day 19
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- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-3119189

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	30 NOV 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.2 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

	Not Done ☐
Fatigue	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-3119192

Symptom Day

- Day 1 ☐
- Day 2 ☐
- Day 3 ☐
- Day 4 ☐
- Day 5 ☐
- Day 6 ■
- Day 7 ☐
- Day 8 ☐
- Day 9 ☐
- Day 10 ☐
- Day 11 ☐
- Day 12 ☐
- Day 13 ☐
- Day 14 ☐
- Day 15 ☐
- Day 16 ☐
- Day 17 ☐
- Day 18 ☐
- Day 19 ☐
- Day 20 ☐
- Day 21 ☐
- Day 22 ☐
- Day 23 ☐
- Day 24 ☐
- Day 25 ☐
- Day 26 ☐
- Day 27 ☐
- Day 28 ☐
- Day 29 ☐
- Day 30 ☐
- Day 31 ☐
- Day 32 ☐

FDA-CBER-2022-1614-3119193

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	01 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.9 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

	Not Done ☐
Fatigue	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
New Loss of Taste	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Nasal Congestion	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [x] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-3119197

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	02 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	99.3 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Nasal Congestion	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

FDA-CBER-2022-1614-3119201

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	03 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.9 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Nasal Congestion	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [x] Day 9
- [ ] Day 10
- [ ] Day 11
- [ ] Day 12
- [ ] Day 13
- [ ] Day 14
- [ ] Day 15
- [ ] Day 16
- [ ] Day 17
- [ ] Day 18
- [ ] Day 19
- [ ] Day 20
- [ ] Day 21
- [ ] Day 22
- [ ] Day 23
- [ ] Day 24
- [ ] Day 25
- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-3119205

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	04 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	99.3 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

	Not Done ☐
Fatigue	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Muscle Aches (Myalgia)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Body Aches	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Headache	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Taste	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
New Loss of Smell	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Nasal Congestion	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **23 Feb 2021 17:18:23**
Generated On: 10 Jun 2021 09:34:30

Date of Visit	30 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ■
Date of Test	30 NOV 2020
Type of Test Performed	Nasopharyngeal Swab ■ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ■
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **23 Feb 2021 17:18:23**
Generated On: 10 Jun 2021 09:34:30

Generate Next COVID-19 Assessment	Yes ☐ No ■

FDA-CBER-2022-1614-3119210

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection
Data signed: (b) (4) **23 Feb 2021 17:18:23**
Generated On: 10 Jun 2021 09:34:30

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	02 DEC 2020
Day 5	Yes	04 DEC 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3742137
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	30 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-3119212

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Were vital signs assessed?	Yes ● / No ○
Date of assessment *(dd MMM yyyy)*	30 NOV 2020
Time of assessment *(00:00-23:59)*	13:05 (24 HR)
Vital Signs Date and Time (derived)	30 NOV 2020 13:05
Height *(xxx.x)*	65.0 in
Weight *(xxx.x)*	171.0 lb
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ● / Axillary ○ / Other ○
If Other, specify	
Pulse *(xxx)*	83 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742137
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	30 NOV 2020

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

US3742137
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **23 Feb 2021 17:18:23**
Generated On: 10 Jun 2021 09:34:30

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	30 NOV 2020

FDA-CBER-2022-1614-3119215

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	27 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-3119216

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **13 Apr 2021 21:39:01**
Generated On: 10 Jun 2021 09:34:30

Date of updated informed consent *(dd MMM yyyy)*	27 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)*	27 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	

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	27 JAN 2021
Collection time *(00:00-23:59)*	14:55 (24 HR)
Collection date and time (derived)	27 JAN 2021 14:55

FDA-CBER-2022-1614-3119218

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **23 Feb 2021 17:18:24**
Generated On: 10 Jun 2021 09:34:30

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	27 JAN 2021
Collection time *(00:00 - 23:59)*	14:59
Collection Date and Time (derived)	27 JAN 2021 14:59

FDA-CBER-2022-1614-3119219

US3742137
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **14 Mar 2021 21:26:46**
Generated On: 10 Jun 2021 09:34:30

Did the participant experience any adverse events?	Yes ■ No ☐

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-3119220

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **23 Apr 2021 17:54:08**
Generated On: 10 Jun 2021 09:34:30

AEID	
Adverse event	OTALGIA
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)*	22 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	26 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

FDA-CBER-2022-1614-3119221

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

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **23 Apr 2021 17:54:08**
Generated On: 10 Jun 2021 09:34:30

AEID	
Adverse event	UPPER RESPIRATORY INFECTION
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)*	26 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	03 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
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	True
Concomitant Medication	False
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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **23 Apr 2021 17:54:08**
Generated On: 10 Jun 2021 09:34:30

AEID	
Adverse event	TINNITUS
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)*	20 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	1 APR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

FDA-CBER-2022-1614-3119225

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	True
Concomitant Medication	False
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:	THE TINNITUS IS RELATED TO HER MIGRAINE HEADACHES. THE TINNITUS WILL RECUR WITH HER CHRONIC MIGRAINES.
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **23 Apr 2021 17:54:08**
Generated On: 10 Jun 2021 09:34:30

AEID	
Adverse event	FATIGUE
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)*	25 SEP 2020
Start time *(00:00-23:59)*	19:23 (24 HR)
AE start date and time (derived)	25 SEP 2020 19:23
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	4 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	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

FDA-CBER-2022-1614-3119227

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	True
Concomitant Medication	False
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	PROLONGED VACCINE REACTOGENICITY
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Data signed: (b) (4) **23 Apr 2021 17:54:08**
Generated On: 10 Jun 2021 09:34:30

AEID	USA-US127-2021-MRNA-1273-P30 1000013
Adverse event	ANAPHYLAXIS
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)*	9 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	9 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
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

	PARTICIPANT HAD ALLERGY TESTING ON 09FEB2021 BECAUSE SHE HAS A HISTORY OF ASTHMA. DURING TESTING HAD AN ALLERGIC REACTION AND WAS GIVEN BENEDRYL,(LIQUID) EPINEPRHRINE (INJECTION). DOSES UNKNOWN.
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)	

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **23 Feb 2021 17:18:23**
Generated On: 10 Jun 2021 09:34:30

Were any prior/concomitant medications and/or vaccinations taken?	Yes ■ No ☐

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

FDA-CBER-2022-1614-3119232

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	XANAX
Prophylaxis	Yes ☐ No ■
Indication	ANXIETY
Dose per administration	0.5
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3119233

	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)*	14 DEC 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 ☐

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	ZOFRAN
Prophylaxis	Yes ☐ No ■
Indication	NAUSEA
Dose per administration	8
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 ☐

FDA-CBER-2022-1614-3119235

	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)*	14 DEC 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 ☐

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	SINGULAIR
Prophylaxis	Yes ☐ No ■
Indication	ASTHMA
Dose per administration	10
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3119237

	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 OCT 2019
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	VALTREX
Prophylaxis	Yes ☐ No ■
Indication	GENITAL HERPES
Dose per administration	500
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	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 DEC 2008
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 ■

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	ALBUTEROL
Prophylaxis	Yes ☐ No ■
Indication	ASTHMA
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 ☐

FDA-CBER-2022-1614-3119241

	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 1998
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 ☐

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	TUMS [CALCIUM CARBONATE]
Prophylaxis	Yes ☐ No ■
Indication	INDIGESTION
Dose per administration	750
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 ☐

FDA-CBER-2022-1614-3119243

	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 1998
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 ☐

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	CLARITIN
Prophylaxis	Yes ☐ No ■
Indication	ASTHMA
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 ☐

FDA-CBER-2022-1614-3119245

	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 OCT 2019
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 ■

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	GENERALIZED PAIN
Dose per administration	800
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3119247

	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 2019
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 ☐

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ■
Indication	GENERALIZED PAIN
Dose per administration	1000
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	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 1998
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 ☐

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	MELATONIN
Prophylaxis	Yes ☐ No ■
Indication	INSOMNIA
Dose per administration	3
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 ☐

FDA-CBER-2022-1614-3119251

	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 ■

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	PAIN AT INJECTION SITE
Dose per administration	800
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ■ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ 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)*	28 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	28 AUG 2020
Was this medication taken for solicited event?	Yes ■
	No ☐
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	SUDAFED
Prophylaxis	Yes ☐ No ■
Indication	OTALGIA
Dose per administration	60
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)*	22 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	23 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 ☐

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ■
Indication	FEVER
Dose per administration	1000
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3119257

	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)*	25 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	27 SEP 2020
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 ■

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	HEADACHE
Dose per administration	800
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ 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)*	25 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	27 SEP 2020
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 ■

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ■ No ☐
Indication	FLU INFLUENZA
Dose per administration	0.5
Dose unit	mg ☐ ug ☐ mL ■ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3119261

	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)*	27 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	27 NOV 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 ☐

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	10
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	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)*	31 DEC 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	TRAZADONE
Prophylaxis	Yes ☐ No ■
Indication	INSOMNIA
Dose per administration	50
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	31 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	EPINEPRHIRNE
Prophylaxis	Yes ☐ No ■
Indication	ANAPHYLAXIS
Dose per administration	0.30
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)*	9 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
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	BENEDRYL
Prophylaxis	Yes ☐ No ■
Indication	ANAPHYLAXIS
Dose per administration	10
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	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)*	9 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	9 FEB 2021
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	SUMATRIPTAN SUCCINATE
Prophylaxis	Yes ☐ No ■
Indication	MIGRAINE HEADACHES
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	AS NEEDED
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)*	17 MAR 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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3742137
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-3119273

US3742137
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
9 FEB 2021	ALLERGY TESTING DUE TO ASTHMA	Medical History	

FDA-CBER-2022-1614-3119274

US3742137
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 10 Jun 2021 09:34:30

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 ☐

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

SAEID	USA-US127-2021-MRNA-1273-P301000013
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form (1)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

SAEID	USA-US127-2021-MRNA-1273-P301000013
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	01/MAR/2021 11:58
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

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form (2)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

SAEID	USA-US127-2021-MRNA-1273-P301000013
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	01/MAR/2021 18:03
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

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form (3)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

SAEID	USA-US127-2021-MRNA-1273-P301000013
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/MAR/2021 07:51
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

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form (4)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

SAEID	USA-US127-2021-MRNA-1273-P301000013
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/MAR/2021 08:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form (5)
Data signed: (b) (4) **07 Apr 2021 21:07:26**
Generated On: 10 Jun 2021 09:34:30

SAEID	USA-US127-2021-MRNA-1273-P301000013
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/MAR/2021 10:33
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

US3742137 (Prod: University of Maryland School of Medicine)

US3742137
Form: Participant Creation
Generated On: 10 Jun 2021 09:34:30
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:10:01
User entered 'US3742137'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:34:48

US3742137
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:20:56
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:43:34

US3742137
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:20:56
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:34:49

US3742137
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
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 05:56:24
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:20:56
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:43:34

US3742137
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered 'SCRN'	System	28 Aug 2020 17:43:34

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered (b) (6) 1980'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:34:50

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered '40'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'YEARS'	System	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '40'	System	28 Aug 2020 17:44:36

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered 'Female (F)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered '1'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:34:30
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:21:48
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:08

US3742137
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:34:30
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:22:13
User entered '28 Aug 2020'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:36

FDA-CBER-2022-1614-3119304

US3742137
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:34:30
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Aug 2020'	System	28 Aug 2020 17:44:36

US3742137
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:34:30
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2020'	System	28 Aug 2020 17:44:36

FDA-CBER-2022-1614-3119306

US3742137
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:34:30
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:22:13
User entered 'Amendment 3 (3)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:36

US3742137
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:34:30
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:22:13
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:36

US3742137
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:34:30
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:22:13
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:36

US3742137
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:34:30
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:22:13
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:36

US3742137
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:34:30
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:22:13
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:36

US3742137
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:34:30
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:22:13
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 15:34:49

US3742137
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:34:30
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '1'	System	28 Aug 2020 17:44:40

US3742137
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 09:34:30
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:22:21
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:44:40

US3742137
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 09:34:30
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:22:27
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:13:59

US3742137
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:31:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:16:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:16:52
Data point term sent to Coder	System	28 Aug 2020 20:15:42
User entered 'Hysterectomy'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:15:19

US3742137
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:20:28
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 15:42:02
User entered '04 Oct 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:42:02
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:31:59
User entered '4 Oct 2019'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:15:19

US3742137
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:31:59
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:15:19

US3742137
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:31:59
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:15:19

US3742137
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:20:28
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 15:42:13
User entered '05 Oct 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:42:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:31:59
User entered '5 Oct 2019'	Sherry McCammon (b) (4)	28 Aug 2020 20:15:19

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US3742137
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:31:59
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:15:19

US3742137
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Oct 2019'	System	28 Aug 2020 20:15:19

US3742137
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2019'	System	28 Aug 2020 20:15:19

FDA-CBER-2022-1614-3119323

US3742137
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Oct 2019'	System	28 Aug 2020 20:15:19

FDA-CBER-2022-1614-3119324

US3742137
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2019'	System	28 Aug 2020 20:15:19

US3742137
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:03
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menometrorrhagia, LLT: Menometrorrhagia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:51:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:51:42
Data point term sent to Coder	System	11 Sep 2020 17:50:41
Coding entries removed.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:50:06
User entered 'MENOMETRORRHAGIA' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:50:06
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menometrorrhagia, LLT: Menometrorrhagia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:32:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:32:20
Data point term sent to Coder	System	28 Aug 2020 20:16:44
User entered 'memomeororrhagia'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:16:19

US3742137
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:20:28
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 15:41:39
User entered '04 Oct 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:41:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:03
User entered '4 Oct 2019'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:16:19

US3742137
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:03
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:16:19

US3742137
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:03
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:16:19

US3742137
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:20:28
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 15:42:34
User entered '05 Oct 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:42:34
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:03
User entered '5 Oct 2019'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:16:19

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US3742137
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:03
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:16:19

US3742137
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Oct 2019'	System	28 Aug 2020 20:16:19

FDA-CBER-2022-1614-3119332

US3742137
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2019'	System	28 Aug 2020 20:16:19

FDA-CBER-2022-1614-3119333

US3742137
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Oct 2019'	System	28 Aug 2020 20:16:19

FDA-CBER-2022-1614-3119334

US3742137
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2019'	System	28 Aug 2020 20:16:19

FDA-CBER-2022-1614-3119335

US3742137
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
User closed query 'Per MM, please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 16:12:05
Query 'Per MM, please include the underlying condition that led to the procedure. ' answered with 'RELATED TO ENDOMETRIOSIS' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:16:16
User opened query 'Per MM, please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 02:15:46
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:06
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Laparoscopy, LLT: Laparoscopy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 05:00:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 05:00:28
Data point term sent to Coder	System	28 Aug 2020 20:17:49
User entered 'abdominal laparoscopy'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:17:18

FDA-CBER-2022-1614-3119336

US3742137
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:06
User entered 'UN Jan 2001' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:45:50
User entered '15 Jan 2001'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:17:18

US3742137
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:06
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:17:18

US3742137
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:06
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:17:18

US3742137
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:06
User entered 'UN Jan 2001' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	11 Sep 2020 17:45:50
User entered '15 Jan 2001'	Sherry McCammon (b) (4)	28 Aug 2020 20:17:18

US3742137
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:06
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:17:18

US3742137
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jan 2001'	System	28 Aug 2020 20:17:18

FDA-CBER-2022-1614-3119342

US3742137
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2001'	System	28 Aug 2020 20:17:18

US3742137
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jan 2001'	System	28 Aug 2020 20:17:18

FDA-CBER-2022-1614-3119344

US3742137
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2001'	System	28 Aug 2020 20:17:18

FDA-CBER-2022-1614-3119345

US3742137
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:20:28
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:19:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:19:42
Data point term sent to Coder	System	28 Aug 2020 20:18:56
User entered 'endometriosis'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:18:20

US3742137
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:20:28
User entered 'UN Jan 2001' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:46:09
User entered '15 Jan 2001'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:18:20

US3742137
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:20:28
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:18:20

US3742137
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:20:28
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:18:20

US3742137
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:20:28
User entered 'UN Jan 2001' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	11 Sep 2020 17:46:09
User entered '15 Jan 2001'	Sherry McCammon (b) (4)	28 Aug 2020 20:18:20

US3742137
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:20:28
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:18:20

US3742137
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jan 2001'	System	28 Aug 2020 20:18:20

US3742137
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2001'	System	28 Aug 2020 20:18:20

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US3742137
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jan 2001'	System	28 Aug 2020 20:18:20

FDA-CBER-2022-1614-3119354

US3742137
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2001'	System	28 Aug 2020 20:18:20

FDA-CBER-2022-1614-3119355

US3742137
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:20:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Bunion operation, LLT: Bunionectomy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:17:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:17:07
Data point term sent to Coder	System	28 Oct 2020 15:45:18
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 15:44:55
Coding entries removed.	(b) (4), (b) (6)	28 Oct 2020 15:44:55
User entered 'BUNIONECTOMY' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:44:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Bunion operation, LLT: Bunionectomy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 09:17:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 09:17:35
Data point term sent to Coder	System	28 Aug 2020 20:21:02
User entered 'Buninectomy'	Sherry McCammon (b) (4)	28 Aug 2020 20:20:30

US3742137
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:20:28
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 15:44:55
User entered '01 Jun 2015' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:44:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:17
User entered '1 Jun 2015'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:20:30

US3742137
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:17
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:20:30

US3742137
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:17
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:20:30

US3742137
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:20:28
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 15:44:55
User entered '01 Jun 2015' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:44:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:17
User entered '1 Jun 2015'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:20:30

US3742137
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:17
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:20:30

US3742137
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jun 2015'	System	28 Aug 2020 20:20:30

US3742137
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2015'	System	28 Aug 2020 20:20:30

FDA-CBER-2022-1614-3119363

US3742137
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jun 2015'	System	28 Aug 2020 20:20:30

FDA-CBER-2022-1614-3119364

US3742137
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2015'	System	28 Aug 2020 20:20:30

FDA-CBER-2022-1614-3119365

US3742137
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:20
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:22:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:22:44
Data point term sent to Coder	System	28 Aug 2020 20:22:08
User entered 'Anxiety'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:21:54

FDA-CBER-2022-1614-3119366

US3742137
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:20
User entered '14 Dec 2010'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:21:54

US3742137
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:20
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:21:54

US3742137
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:20
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:21:54

US3742137
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:20
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:21:54

US3742137
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:20
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:21:54

US3742137
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Dec 2010'	System	28 Aug 2020 20:21:54

US3742137
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2010'	System	28 Aug 2020 20:21:54

FDA-CBER-2022-1614-3119373

US3742137
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:21:54

US3742137
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:21:54

US3742137
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:32:24
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:23:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:23:41
Data point term sent to Coder	System	28 Aug 2020 20:23:09
User entered 'Asthma'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:22:36

US3742137
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:24
User entered 'UN UNK 1988' reason for change: New Information	Kaitlin Mason (b) (4)	11 Sep 2020 17:47:07
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	28 Aug 2020 20:26:05
User entered '30 Jun 1988' reason for change: New Information	Sherry McCammon (b) (4)	28 Aug 2020 20:26:05
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	28 Aug 2020 20:22:36
User entered empty.	Sherry McCammon (b) (4)	28 Aug 2020 20:22:36

US3742137
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:24
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:22:36

US3742137
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:24
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:22:36

US3742137
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:24
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:22:36

US3742137
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:24
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:22:36

US3742137
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jan 1988'	System	11 Sep 2020 17:47:07
User entered 'Jun 1988'	System	28 Aug 2020 20:26:05
User entered empty.	System	28 Aug 2020 20:22:36

US3742137
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '1988'	System	28 Aug 2020 20:26:05
User entered empty.	System	28 Aug 2020 20:22:36

FDA-CBER-2022-1614-3119383

US3742137
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:22:36

US3742137
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:22:36

FDA-CBER-2022-1614-3119385

US3742137
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:26
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Genital herpes, LLT: Genital herpes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:23:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:23:41
Data point term sent to Coder	System	28 Aug 2020 20:23:10
User entered 'Genital Herpes'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:23:07

US3742137
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:26
User entered 'UN UNK 2008' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:47:21
User entered '30 Jun 2008'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:23:07

US3742137
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:26
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:23:07

US3742137
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:26
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:23:07

US3742137
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:26
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:23:07

US3742137
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:26
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:23:07

US3742137
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jan 2008'	System	11 Sep 2020 17:47:21
User entered 'Jun 2008'	System	28 Aug 2020 20:23:07

US3742137
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2008'	System	28 Aug 2020 20:23:07

FDA-CBER-2022-1614-3119393

US3742137
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:23:07

US3742137
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:23:07

FDA-CBER-2022-1614-3119395

US3742137
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:32:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Indigestion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:49:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:49:45
Data point term sent to Coder	System	11 Sep 2020 17:48:37
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	11 Sep 2020 17:48:02
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'INDIGESTION' (Site from System).	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:48:02
User entered 'INDIGESTION' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:47:57
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4) (b) (4)	07 Sep 2020 20:40:29
Data point term sent to Coder	System	28 Aug 2020 20:24:12
User entered 'Indigestion/ Heartburn'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:23:44

US3742137
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:30
User entered 'UN UNK 1998' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:47:57
User entered '30 Jun 1998'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:23:44

US3742137
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:30
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:23:44

US3742137
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:32:30
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 20:26:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 20:26:47
User entered 'Yes (Y)' reason for change: New Information	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:26:47
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 20:23:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:23:44

US3742137
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:23:44

US3742137
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:30
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:23:44

US3742137
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jan 1998'	System	11 Sep 2020 17:47:57
User entered 'Jun 1998'	System	28 Aug 2020 20:23:44

US3742137
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '1998'	System	28 Aug 2020 20:23:44

US3742137
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:23:44

US3742137
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:23:44

US3742137
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:32
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)	28 Aug 2020 20:25:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:25:44
Data point term sent to Coder	System	28 Aug 2020 20:24:13
User entered 'Insomnia'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:24:11

US3742137
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:32
User entered 'UN UNK 2015' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:48:18
User entered '30 Jun 2015'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:24:11

US3742137
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:32
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:24:11

US3742137
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:32
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:24:11

US3742137
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:32
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:24:11

US3742137
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:32
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:24:11

US3742137
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jan 2015'	System	11 Sep 2020 17:48:18
User entered 'Jun 2015'	System	28 Aug 2020 20:24:11

US3742137
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2015'	System	28 Aug 2020 20:24:11

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US3742137
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:24:11

US3742137
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:24:11

FDA-CBER-2022-1614-3119415

US3742137
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:32:34
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Contrast media allergy, LLT: Contrast media allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 20:55:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 20:55:39
Data point term sent to Coder	System	28 Aug 2020 20:25:14
User entered 'Allergy to contrast dye (sneezing)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:24:47

US3742137
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:34
User entered '22 Nov 2013'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:24:47

US3742137
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:34
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:24:47

US3742137
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:34
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:24:47

US3742137
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:34
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:24:47

US3742137
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:34
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:24:47

US3742137
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Nov 2013'	System	28 Aug 2020 20:24:47

US3742137
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2013'	System	28 Aug 2020 20:24:47

FDA-CBER-2022-1614-3119423

US3742137
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:24:47

US3742137
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:24:47

US3742137
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:32:38
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Vegetable allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 20:53:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 20:53:38
Data point term sent to Coder	System	28 Aug 2020 20:26:15
User entered 'Allergy to avocodo'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:25:20

US3742137
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:38
User entered 'UN UNK 2015' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:48:52
User entered '30 Jun 2015'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:25:20

US3742137
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:38
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:25:20

US3742137
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:32:38
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 20:35:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 20:35:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:35:53
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 20:25:20
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:25:20

US3742137
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:38
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:25:20

US3742137
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:38
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:25:20

US3742137
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jan 2015'	System	11 Sep 2020 17:48:52
User entered 'Jun 2015'	System	28 Aug 2020 20:25:20

US3742137
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2015'	System	28 Aug 2020 20:25:20

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US3742137
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:25:20

US3742137
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	28 Aug 2020 20:25:20

US3742137
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:20:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 12:42:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 12:42:18
Data point term sent to Coder	System	06 Oct 2020 12:41:11
User entered 'GENERALIZED PAIN'	(b) (4), (b) (6)	06 Oct 2020 12:40:21

US3742137
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:20:28
User entered 'UN UNK 1998'	(b) (4), (b) (6)	06 Oct 2020 12:40:21

US3742137
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:20:28
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 12:40:21

US3742137
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:20:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:40:21

US3742137
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:20:28
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 12:40:21

FDA-CBER-2022-1614-3119440

US3742137
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:20:28
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 12:40:21

FDA-CBER-2022-1614-3119441

US3742137
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jan 1998'	System	06 Oct 2020 12:40:21

FDA-CBER-2022-1614-3119442

US3742137
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '1998'	System	06 Oct 2020 12:40:21

FDA-CBER-2022-1614-3119443

US3742137
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	06 Oct 2020 12:40:21

FDA-CBER-2022-1614-3119444

US3742137
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	06 Oct 2020 12:40:21

FDA-CBER-2022-1614-3119445

US3742137
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:02:04
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
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)	06 Jan 2021 16:45:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Jan 2021 16:45:41
Data point term sent to Coder	System	06 Jan 2021 16:45:00
User entered 'HYPERTENSION'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:01

US3742137
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:02:04
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
User entered 'UN Sep 2019'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:01

US3742137
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:02:04
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
User entered '0'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:01

US3742137
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:02:04
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:01

FDA-CBER-2022-1614-3119449

US3742137
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:02:04
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:01

FDA-CBER-2022-1614-3119450

US3742137
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:02:04
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
User entered '0'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:01

FDA-CBER-2022-1614-3119451

US3742137
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Sep 2019'	System	06 Jan 2021 16:44:01

FDA-CBER-2022-1614-3119452

US3742137
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2019'	System	06 Jan 2021 16:44:01

FDA-CBER-2022-1614-3119453

US3742137
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	06 Jan 2021 16:44:01

FDA-CBER-2022-1614-3119454

US3742137
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	06 Jan 2021 16:44:01

FDA-CBER-2022-1614-3119455

US3742137
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:34:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:11:55
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	25 Mar 2021 17:50:21
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 13:59:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 13:59:35
Data point term sent to Coder	System	24 Mar 2021 13:59:24
User entered 'Migraines Headaches'	(b) (4), (b) (6)	24 Mar 2021 13:58:28

US3742137
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:34:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:11:55
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	25 Mar 2021 17:50:21
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	24 Mar 2021 18:34:52
User entered 'UN UNK 2001' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 18:34:52
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	24 Mar 2021 13:58:28
User entered 'UN UNK 2021'	(b) (4), (b) (6)	24 Mar 2021 13:58:28

US3742137
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:11:55
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	25 Mar 2021 17:50:21
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 13:58:28

US3742137
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:34:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:11:55
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	25 Mar 2021 17:50:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 13:58:28

US3742137
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:34:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:11:55
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	25 Mar 2021 17:50:21
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:58:28

US3742137
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:34:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:11:55
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	25 Mar 2021 17:50:21
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 13:58:28

US3742137
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:34:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered 'Jan 2001'	System	24 Mar 2021 18:34:52
User entered 'Jan 2021'	System	24 Mar 2021 13:58:28

US3742137
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:34:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered '2001'	System	24 Mar 2021 18:34:52
User entered '2021'	System	24 Mar 2021 13:58:28

US3742137
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:34:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	24 Mar 2021 13:58:28

US3742137
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:34:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User entered empty.	System	24 Mar 2021 13:58:28

FDA-CBER-2022-1614-3119465

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:53:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:14:13

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:53:29
User entered '28 Aug 2020'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:14:13

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:53:29
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:34:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 20:34:50
User entered '11:37' reason for change: New Information	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:34:50
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:14:13
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:14:13

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered '28 Aug 2020 11:37'	System	28 Aug 2020 20:34:50
User entered empty.	System	28 Aug 2020 20:14:13

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:53:29
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:34:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 20:34:50
User entered '64.0' in reason for change: New Information	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:34:50
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:14:13
User entered empty.	Sherry McCammon (b) (4)	28 Aug 2020 20:14:13
DataPoint set to visible.	(b) (4) System	28 Aug 2020 17:44:40

FDA-CBER-2022-1614-3119470

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:53:29
User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	21 Sep 2020 18:59:45
Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered by data change (Site from System).	System	21 Sep 2020 18:59:45
User entered '170' lb reason for change: New Information	Kaitlin Mason (b) (4)	21 Sep 2020 18:59:45
Amendment Manager: User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	17 Sep 2020 00:09:28
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:34:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 20:34:50
User entered '64.0' lb reason for change: New Information	Sherry McCammon (b) (4)	28 Aug 2020 20:34:50
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:14:13
User entered empty.	Sherry McCammon (b) (4)	28 Aug 2020 20:14:13
DataPoint set to visible.	System	28 Aug 2020 17:44:40

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered '29.24145'	System	21 Sep 2020 18:59:45
User entered '11.00854'	System	28 Aug 2020 20:34:50
User entered empty.	System	28 Aug 2020 20:14:13
DataPoint set to visible.	System	28 Aug 2020 17:44:40

FDA-CBER-2022-1614-3119472

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered 'kg/m2'	System	28 Aug 2020 20:34:50
User entered empty.	System	28 Aug 2020 20:14:13
DataPoint set to visible.	System	28 Aug 2020 17:44:40

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:53:29
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 18:59:39
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:00:26
User entered missing code ND - Not Done; reason for change New Information	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:00:20
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 20:28:02
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:34:50

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 20:34:50
User entered '098.8' F reason for change: New Information	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:34:50
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:14:13
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:14:13

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:53:29
User entered empty; reason for change New Information	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:00:20
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:35:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 20:35:02
User entered 'Oral (Oral)' reason for change: New Information	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:35:02
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:34:50
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:14:13

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US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:53:29
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:14:13

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:53:29
User entered missing code ND - Not Done; reason for change New Information	Kaitlin Mason (b) (4)	21 Sep 2020 19:00:20
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:34:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 20:34:50
User entered '086' reason for change: New Information	Sherry McCammon (b) (4)	28 Aug 2020 20:34:50
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:14:13
User entered empty.	Sherry McCammon (b) (4)	28 Aug 2020 20:14:13

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered 'bpm'	System	28 Aug 2020 20:34:50
User entered empty.	System	28 Aug 2020 20:14:13

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:53:29
User entered missing code ND - Not Done; reason for change New Information	Kaitlin Mason (b) (4)	21 Sep 2020 19:00:20
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:34:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 20:34:50
User entered '14' reason for change: New Information	Sherry McCammon (b) (4)	28 Aug 2020 20:34:50
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:14:13
User entered empty.	Sherry McCammon (b) (4)	28 Aug 2020 20:14:13

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered 'breaths/min'	System	28 Aug 2020 20:34:50
User entered empty.	System	28 Aug 2020 20:14:13

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:53:29
User entered missing code ND - Not Done; reason for change New Information	Kaitlin Mason (b) (4)	21 Sep 2020 19:00:20
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:34:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 20:34:50
User entered '123' reason for change: New Information	Sherry McCammon (b) (4)	28 Aug 2020 20:34:50
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:14:13
User entered empty.	Sherry McCammon (b) (4)	28 Aug 2020 20:14:13

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US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered 'mmHg'	System	28 Aug 2020 20:34:50
User entered empty.	System	28 Aug 2020 20:14:13

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:53:29
User entered missing code ND - Not Done; reason for change New Information	Kaitlin Mason (b) (4)	21 Sep 2020 19:00:20
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:34:50
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 20:34:50
User entered '085' reason for change: New Information	Sherry McCammon (b) (4)	28 Aug 2020 20:34:50
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:14:13
User entered empty.	Sherry McCammon (b) (4)	28 Aug 2020 20:14:13

FDA-CBER-2022-1614-3119484

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered 'mmHg'	System	28 Aug 2020 20:34:50
User entered empty.	System	28 Aug 2020 20:14:13

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24

FDA-CBER-2022-1614-3119486

US3742137
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24

FDA-CBER-2022-1614-3119487

US3742137
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:34:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:06
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:13:27

US3742137
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:34:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:06
User entered '28 Aug 2020'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:13:27

US3742137
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:34:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:41
User entered '28 Aug 2020'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:29:06

US3742137
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:34:30
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:41
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:29:06

US3742137
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:34:30
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:54:41
User entered 'Surgically sterile (SURGICALLY STERILE)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:29:06

US3742137
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:34:30
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:41
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:29:06

US3742137
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:34:30
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:41
User entered '4 Oct 2019'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:29:06

US3742137
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:34:30
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:41
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:29:06

US3742137
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:34:30
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:41
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:29:06

US3742137
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:34:30
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:41
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:29:06

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
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)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
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)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
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)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
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)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
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)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
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)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:54:58
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 17:45:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 17:45:36
User entered 'No (N)' reason for change: New Information	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:36
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 17:45:28
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
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)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
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)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
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)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
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)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
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 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered '1'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
User entered '0'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:34:30
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:21
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:54:58
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:45:28

US3742137
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:57:47
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	28 Aug 2020 20:12:22

US3742137
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:57:47
User entered '28 Aug 2020'	Sherry McCammon (b) (4)	28 Aug 2020 20:12:22

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US3742137
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:57:47
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	28 Aug 2020 20:12:22

US3742137
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'VISIT1'	System	28 Aug 2020 20:12:22

FDA-CBER-2022-1614-3119522

US3742137
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:34:30
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:03:36
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:04:43

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US3742137
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:34:30
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:03:36
User entered '109479'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:04:43

US3742137
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:34:30
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:03:36
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:04:43

FDA-CBER-2022-1614-3119525

US3742137
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:34:30
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)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:03:36
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:12:57

US3742137
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:34:30

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)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:03:36
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:12:57

FDA-CBER-2022-1614-3119527

US3742137
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:34:30
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:03:36
User entered 'No (N)'	Sherry McCammon (b) (4)	28 Aug 2020 20:12:57

US3742137
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:34:30
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:03:36
User entered 'No (N)'	Sherry McCammon (b) (4)	28 Aug 2020 20:12:57

US3742137
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:34:30
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:03:36
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:12:57

US3742137
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:34:30
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:20:50
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 17:03:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:03:36
User entered 'No (N)'	Kaitlin Mason (b) (4)	21 Sep 2020 19:00:48
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:26:32
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:26:31

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:34:30
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:06:53
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:53:02
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 18:58:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 18:58:10
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 20:28:07
User entered '64.0' in	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

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US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:34:30
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 18:58:10
User entered '170.0' lb	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:34:30
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:06:53
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:53:02
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 18:58:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 18:58:10
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 20:28:07
User entered '64.0' in	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

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US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:34:30
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 18:58:10
User entered '170.0' lb	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

FDA-CBER-2022-1614-3119536

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '28 Aug 2020'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '11:37'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '28 Aug 2020 11:37'	System	28 Aug 2020 20:33:02

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US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '098.8' F	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered empty.	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '086'	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'bpm'	System	28 Aug 2020 20:33:02

FDA-CBER-2022-1614-3119545

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '14'	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

FDA-CBER-2022-1614-3119546

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'breaths/min'	System	28 Aug 2020 20:33:02

FDA-CBER-2022-1614-3119547

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '123'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'mmHg'	System	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '085'	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

FDA-CBER-2022-1614-3119550

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'mmHg'	System	28 Aug 2020 20:33:02

FDA-CBER-2022-1614-3119551

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:34:30
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:06:53
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:53:02
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 18:58:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 18:58:10
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 20:28:07
User entered '64.0' in	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:34:30
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 18:58:10
User entered '170.0' lb	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '28 Aug 2020'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '14:12'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '28 Aug 2020 14:12'	System	28 Aug 2020 20:33:02

FDA-CBER-2022-1614-3119558

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '97.9' F	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered 'Other (Other)'	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered 'Forehead'	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '086'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'bpm'	System	28 Aug 2020 20:33:02

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US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '16'	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'breaths/min'	System	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '139'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'mmHg'	System	28 Aug 2020 20:33:02

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US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:06:53
User entered '078'	Sherry McCammon (b) (4)	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'mmHg'	System	28 Aug 2020 20:33:02

US3742137
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:34:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:07:07
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 19:03:36
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' answered with 'ENTERED IN ERROR UPDATED' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:38:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:37:59
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 20:28:14
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:10

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US3742137
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:34:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:07:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:37:59
User entered '28 Aug 2020'	Sherry McCammon (b) (4) (b) (4)	28 Aug 2020 20:33:10

US3742137
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:07:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:01:54

US3742137
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:07:27
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:01:54

US3742137
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:07:27
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:01:54

US3742137
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 18:01:54

US3742137
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:07:27
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:01:54

US3742137
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:07:27
User entered '13:41'	(b) (4), (b) (6)	28 Aug 2020 18:01:54

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US3742137
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '28 Aug 2020 13:41'	System	28 Aug 2020 18:01:54

US3742137
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:07:27
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	28 Aug 2020 18:01:54

US3742137
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:07:27
User entered 'ONCE'	System	28 Aug 2020 18:01:54

US3742137
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 18:01:54

US3742137
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:07:36
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:46:21

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US3742137
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:07:36
User entered '28 Aug 2020'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:46:21

US3742137
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:07:36
User entered '12:39'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:46:21

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US3742137
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '28 Aug 2020 12:39'	System	28 Aug 2020 17:46:21

US3742137
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:34:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:08:04
User entered '28 Aug 2020'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:46:40

US3742137
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:34:30
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:46:40

US3742137
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:34:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:08:04
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:46:40

US3742137
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:34:30
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:08:04
User entered '12:43'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:46:40

US3742137
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:34:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '28 Aug 2020 12:43'	System	28 Aug 2020 17:46:40

US3742137
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:34:30
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:46:40

US3742137
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:34:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:08:04
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:46:40

US3742137
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:34:30
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:08:04
User entered empty.	Hassan Haji (b) (4) (b) (4)	28 Aug 2020 17:46:40

US3742137
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:34:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered empty.	System	28 Aug 2020 17:46:40

FDA-CBER-2022-1614-3119594

US3742137
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:08:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	28 Aug 2020 20:33:18

US3742137
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '1'	System	28 Aug 2020 20:33:18

FDA-CBER-2022-1614-3119596

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:15:25', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'dddbd0bf-fd5b-4d2b-b9c9-7dff37a6fd0a'	System	28 Aug 2020 18:15:43
User entered 'Yes (Y)'	System	28 Aug 2020 18:15:43

FDA-CBER-2022-1614-3119598

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:15:30', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'dddbd0bf-fd5b-4d2b-b9c9-7dff37a6fd0a'	System	28 Aug 2020 18:15:43
User entered '97.9'	System	28 Aug 2020 18:15:43

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:15:34', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'dddbd0bf-fd5b-4d2b-b9c9-7dff37a6fd0a'	System	28 Aug 2020 18:15:43
User entered 'No (N)'	System	28 Aug 2020 18:15:43

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US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:15:37', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'dddbd0bf-fd5b-4d2b-b9c9-7dff37a6fd0a'	System	28 Aug 2020 18:15:43
User entered '28 Aug 2020 14:15'	System	28 Aug 2020 18:15:43

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Aug 2020 14:01'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119602

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Aug 2020 16:31'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119603

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:22:12', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '914a4434-8b9f-494f-9f90-b40b82800a53'	System	29 Aug 2020 01:22:52
User entered 'Yes (Y)'	System	29 Aug 2020 01:22:52

FDA-CBER-2022-1614-3119605

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:22:41', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '914a4434-8b9f-494f-9f90-b40b82800a53'	System	29 Aug 2020 01:22:52
User entered '99.1'	System	29 Aug 2020 01:22:52

FDA-CBER-2022-1614-3119606

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:22:45', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '914a4434-8b9f-494f-9f90-b40b82800a53'	System	29 Aug 2020 01:22:52
User entered 'No (N)'	System	29 Aug 2020 01:22:52

FDA-CBER-2022-1614-3119607

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:22:51', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '914a4434-8b9f-494f-9f90-b40b82800a53'	System	29 Aug 2020 01:22:52
User entered '28 Aug 2020 21:22'	System	29 Aug 2020 01:22:52

FDA-CBER-2022-1614-3119608

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Aug 2020 17:26'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119609

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119610

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 2'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119611

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:41:29', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b3e71a06-995b-45c8-af1d-a87854cb33f2'	System	29 Aug 2020 17:41:45
User entered 'Yes (Y)'	System	29 Aug 2020 17:41:45

FDA-CBER-2022-1614-3119612

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:41:33', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b3e71a06-995b-45c8-af1d-a87854cb33f2'	System	29 Aug 2020 17:41:45
User entered '98.8'	System	29 Aug 2020 17:41:45

FDA-CBER-2022-1614-3119613

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:41:38', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b3e71a06-995b-45c8-af1d-a87854cb33f2'	System	29 Aug 2020 17:41:45
User entered 'No (N)'	System	29 Aug 2020 17:41:45

FDA-CBER-2022-1614-3119614

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:41:42', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b3e71a06-995b-45c8-af1d-a87854cb33f2'	System	29 Aug 2020 17:41:45
User entered '29 Aug 2020 13:41'	System	29 Aug 2020 17:41:45

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119616

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119617

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 3'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:23:20', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'c463cda8-8134-4363-b7f3-d6a15362d603'	System	30 Aug 2020 17:23:33
User entered 'Yes (Y)'	System	30 Aug 2020 17:23:33

FDA-CBER-2022-1614-3119619

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:23:26', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'c463cda8-8134-4363-b7f3-d6a15362d603'	System	30 Aug 2020 17:23:33
User entered '98.8'	System	30 Aug 2020 17:23:33

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:23:29', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'c463cda8-8134-4363-b7f3-d6a15362d603'	System	30 Aug 2020 17:23:33
User entered 'No (N)'	System	30 Aug 2020 17:23:33

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:23:31', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'c463cda8-8134-4363-b7f3-d6a15362d603'	System	30 Aug 2020 17:23:33
User entered '30 Aug 2020 13:23'	System	30 Aug 2020 17:23:33

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119623

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119624

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 4'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119625

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:24:53', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '21fc8160-99a5-4c1c-b640-871bdbbc576c'	System	31 Aug 2020 22:25:09
User entered 'Yes (Y)'	System	31 Aug 2020 22:25:09

FDA-CBER-2022-1614-3119626

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:24:57', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '21fc8160-99a5-4c1c-b640-871bdbbc576c'	System	31 Aug 2020 22:25:09
User entered '99.1'	System	31 Aug 2020 22:25:09

FDA-CBER-2022-1614-3119627

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '21fc8160-99a5-4c1c-b640-871bdbbc576c'	System	31 Aug 2020 22:25:09
User entered 'No (N)'	System	31 Aug 2020 22:25:09

FDA-CBER-2022-1614-3119628

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:02', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '21fc8160-99a5-4c1c-b640-871bdbbc576c'	System	31 Aug 2020 22:25:09
User entered '31 Aug 2020 18:25'	System	31 Aug 2020 22:25:09

FDA-CBER-2022-1614-3119629

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119630

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119631

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 5'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119632

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:36:58', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9f719bb7-0f49-4b1b-b295-881ec2b425ed'	System	01 Sep 2020 22:37:06
User entered 'No (N)'	System	01 Sep 2020 22:37:06

FDA-CBER-2022-1614-3119633

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:01', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9f719bb7-0f49-4b1b-b295-881ec2b425ed'	System	01 Sep 2020 22:37:06
User entered 'No (N)'	System	01 Sep 2020 22:37:06

FDA-CBER-2022-1614-3119634

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:03', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9f719bb7-0f49-4b1b-b295-881ec2b425ed'	System	01 Sep 2020 22:37:06
User entered '01 Sep 2020 18:37'	System	01 Sep 2020 22:37:06

FDA-CBER-2022-1614-3119635

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119636

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119637

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 6'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119638

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:01:51', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b187ac7c-a20d-410c-bf3f-b206993ac997'	System	02 Sep 2020 21:01:59
User entered 'Yes (Y)'	System	02 Sep 2020 21:01:59

FDA-CBER-2022-1614-3119639

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:01:19', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b187ac7c-a20d-410c-bf3f-b206993ac997'	System	02 Sep 2020 21:01:59
User entered '99.1'	System	02 Sep 2020 21:01:59

FDA-CBER-2022-1614-3119640

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:01:22', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b187ac7c-a20d-410c-bf3f-b206993ac997'	System	02 Sep 2020 21:01:59
User entered 'No (N)'	System	02 Sep 2020 21:01:59

FDA-CBER-2022-1614-3119641

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:01:57', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b187ac7c-a20d-410c-bf3f-b206993ac997'	System	02 Sep 2020 21:01:59
User entered '02 Sep 2020 17:01'	System	02 Sep 2020 21:01:59

FDA-CBER-2022-1614-3119642

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119643

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119644

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 7'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119645

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:21:17', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9817140a-5fda-4bed-be9f-5d9ec2756f70'	System	04 Sep 2020 00:21:41
User entered 'Yes (Y)'	System	04 Sep 2020 00:21:41

FDA-CBER-2022-1614-3119646

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:21:32', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9817140a-5fda-4bed-be9f-5d9ec2756f70'	System	04 Sep 2020 00:21:41
User entered '99.3'	System	04 Sep 2020 00:21:41

FDA-CBER-2022-1614-3119647

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:21:37', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9817140a-5fda-4bed-be9f-5d9ec2756f70'	System	04 Sep 2020 00:21:41
User entered 'No (N)'	System	04 Sep 2020 00:21:41

FDA-CBER-2022-1614-3119648

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:21:39', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9817140a-5fda-4bed-be9f-5d9ec2756f70'	System	04 Sep 2020 00:21:41
User entered '03 Sep 2020 20:21'	System	04 Sep 2020 00:21:41

FDA-CBER-2022-1614-3119649

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119650

US3742137
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119651

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:08', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'fcbb1149-8966-438e-a1d0-52dde6ec18e5'	System	28 Aug 2020 18:16:26
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 18:16:26

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:13', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'fcbb1149-8966-438e-a1d0-52dde6ec18e5'	System	28 Aug 2020 18:16:26
User entered 'No (N)'	System	28 Aug 2020 18:16:26

FDA-CBER-2022-1614-3119654

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:15', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'fcbb1149-8966-438e-a1d0-52dde6ec18e5'	System	28 Aug 2020 18:16:26
User entered 'No (N)'	System	28 Aug 2020 18:16:26

FDA-CBER-2022-1614-3119655

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:19', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'fcbb1149-8966-438e-a1d0-52dde6ec18e5'	System	28 Aug 2020 18:16:26
User entered 'None (1)'	System	28 Aug 2020 18:16:26

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:21', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'fcbb1149-8966-438e-a1d0-52dde6ec18e5'	System	28 Aug 2020 18:16:26
User entered '28 Aug 2020 14:16'	System	28 Aug 2020 18:16:26

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Aug 2020 14:01'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119658

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Aug 2020 16:31'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119659

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:23:23', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '003fc760-b2aa-41b3-9477-5f4d89b8d6c2'	System	29 Aug 2020 01:24:06
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	29 Aug 2020 01:24:06

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:23:28', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '003fc760-b2aa-41b3-9477-5f4d89b8d6c2'	System	29 Aug 2020 01:24:06
User entered 'No (N)'	System	29 Aug 2020 01:24:06

FDA-CBER-2022-1614-3119662

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:23:51', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '003fc760-b2aa-41b3-9477-5f4d89b8d6c2'	System	29 Aug 2020 01:24:06
User entered 'No (N)'	System	29 Aug 2020 01:24:06

FDA-CBER-2022-1614-3119663

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:24:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '003fc760-b2aa-41b3-9477-5f4d89b8d6c2'	System	29 Aug 2020 01:24:06
User entered 'None (1)'	System	29 Aug 2020 01:24:06

FDA-CBER-2022-1614-3119664

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:24:05', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '003fc760-b2aa-41b3-9477-5f4d89b8d6c2'	System	29 Aug 2020 01:24:06
User entered '28 Aug 2020 21:24'	System	29 Aug 2020 01:24:06

FDA-CBER-2022-1614-3119665

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Aug 2020 17:26'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119667

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 2'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119668

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:41:55', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'dc50b1d3-d9df-4b1d-beda-8894ae8483b4'	System	29 Aug 2020 17:42:59
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 17:42:59

FDA-CBER-2022-1614-3119669

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:42:24', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'dc50b1d3-d9df-4b1d-beda-8894ae8483b4'	System	29 Aug 2020 17:42:59
User entered 'No (N)'	System	29 Aug 2020 17:42:59

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:42:36', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'dc50b1d3-d9df-4b1d-beda-8894ae8483b4'	System	29 Aug 2020 17:42:59
User entered 'Yes (Y)'	System	29 Aug 2020 17:42:59

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:42:45', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'dc50b1d3-d9df-4b1d-beda-8894ae8483b4'	System	29 Aug 2020 17:42:59
User entered '1'	System	29 Aug 2020 17:42:59

FDA-CBER-2022-1614-3119672

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:42:54', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'dc50b1d3-d9df-4b1d-beda-8894ae8483b4'	System	29 Aug 2020 17:42:59
User entered 'None (1)'	System	29 Aug 2020 17:42:59

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:42:57', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'dc50b1d3-d9df-4b1d-beda-8894ae8483b4'	System	29 Aug 2020 17:42:59
User entered '29 Aug 2020 13:42'	System	29 Aug 2020 17:42:59

FDA-CBER-2022-1614-3119674

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119675

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119676

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 3'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119677

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:23:45', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '297d8c7d-f22c-4423-9f8b-5e6d0bcffb43'	System	30 Aug 2020 17:24:24
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 17:24:24

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:24:03', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '297d8c7d-f22c-4423-9f8b-5e6d0bcffb43'	System	30 Aug 2020 17:24:24
User entered 'No (N)'	System	30 Aug 2020 17:24:24

FDA-CBER-2022-1614-3119679

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:24:08', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '297d8c7d-f22c-4423-9f8b-5e6d0bcffb43'	System	30 Aug 2020 17:24:24
User entered 'No (N)'	System	30 Aug 2020 17:24:24

FDA-CBER-2022-1614-3119680

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:24:21', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '297d8c7d-f22c-4423-9f8b-5e6d0bcffb43'	System	30 Aug 2020 17:24:24
User entered 'None (1)'	System	30 Aug 2020 17:24:24

FDA-CBER-2022-1614-3119681

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:24:23', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '297d8c7d-f22c-4423-9f8b-5e6d0bcffb43'	System	30 Aug 2020 17:24:24
User entered '30 Aug 2020 13:24'	System	30 Aug 2020 17:24:24

FDA-CBER-2022-1614-3119682

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119683

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119684

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 4'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119685

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:08', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'bc099243-7418-4d6d-bf35-ace6fe150b48'	System	31 Aug 2020 22:25:28
User entered 'None (1)'	System	31 Aug 2020 22:25:28

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:11', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'bc099243-7418-4d6d-bf35-ace6fe150b48'	System	31 Aug 2020 22:25:28
User entered 'No (N)'	System	31 Aug 2020 22:25:28

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:13', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'bc099243-7418-4d6d-bf35-ace6fe150b48'	System	31 Aug 2020 22:25:28
User entered 'No (N)'	System	31 Aug 2020 22:25:28

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:20', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'bc099243-7418-4d6d-bf35-ace6fe150b48'	System	31 Aug 2020 22:25:28
User entered 'None (1)'	System	31 Aug 2020 22:25:28

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:22', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'bc099243-7418-4d6d-bf35-ace6fe150b48'	System	31 Aug 2020 22:25:28
User entered '31 Aug 2020 18:25'	System	31 Aug 2020 22:25:28

FDA-CBER-2022-1614-3119690

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119691

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119692

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 5'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119693

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:06', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'caf51b37-4f69-4879-8f6c-db4d8dd9fad3'	System	01 Sep 2020 22:37:19
User entered 'None (1)'	System	01 Sep 2020 22:37:19

FDA-CBER-2022-1614-3119694

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:10', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'caf51b37-4f69-4879-8f6c-db4d8dd9fad3'	System	01 Sep 2020 22:37:19
User entered 'No (N)'	System	01 Sep 2020 22:37:19

FDA-CBER-2022-1614-3119695

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:12', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'caf51b37-4f69-4879-8f6c-db4d8dd9fad3'	System	01 Sep 2020 22:37:19
User entered 'No (N)'	System	01 Sep 2020 22:37:19

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:15', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'caf51b37-4f69-4879-8f6c-db4d8dd9fad3'	System	01 Sep 2020 22:37:19
User entered 'None (1)'	System	01 Sep 2020 22:37:19

FDA-CBER-2022-1614-3119697

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:17', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'caf51b37-4f69-4879-8f6c-db4d8dd9fad3'	System	01 Sep 2020 22:37:19
User entered '01 Sep 2020 18:37'	System	01 Sep 2020 22:37:19

FDA-CBER-2022-1614-3119698

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119700

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 6'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119701

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:01', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'aa083266-c4ea-4d2e-acb1-6aaae611b040'	System	02 Sep 2020 21:02:11
User entered 'None (1)'	System	02 Sep 2020 21:02:11

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:03', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'aa083266-c4ea-4d2e-acb1-6aaae611b040'	System	02 Sep 2020 21:02:11
User entered 'No (N)'	System	02 Sep 2020 21:02:11

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:05', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'aa083266-c4ea-4d2e-acb1-6aaae611b040'	System	02 Sep 2020 21:02:11
User entered 'No (N)'	System	02 Sep 2020 21:02:11

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:08', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'aa083266-c4ea-4d2e-acb1-6aaae611b040'	System	02 Sep 2020 21:02:11
User entered 'None (1)'	System	02 Sep 2020 21:02:11

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:10', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'aa083266-c4ea-4d2e-acb1-6aaae611b040'	System	02 Sep 2020 21:02:11
User entered '02 Sep 2020 17:02'	System	02 Sep 2020 21:02:11

FDA-CBER-2022-1614-3119706

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119707

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119708

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 7'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119709

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:21:43', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b2f39649-4f41-44b8-ad2c-123a5c1adbbe'	System	04 Sep 2020 00:21:57
User entered 'None (1)'	System	04 Sep 2020 00:21:57

FDA-CBER-2022-1614-3119710

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:21:45', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b2f39649-4f41-44b8-ad2c-123a5c1adbbe'	System	04 Sep 2020 00:21:57
User entered 'No (N)'	System	04 Sep 2020 00:21:57

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:21:48', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b2f39649-4f41-44b8-ad2c-123a5c1adbbe'	System	04 Sep 2020 00:21:57
User entered 'No (N)'	System	04 Sep 2020 00:21:57

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:21:50', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b2f39649-4f41-44b8-ad2c-123a5c1adbbe'	System	04 Sep 2020 00:21:57
User entered 'None (1)'	System	04 Sep 2020 00:21:57

FDA-CBER-2022-1614-3119713

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:21:53', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'b2f39649-4f41-44b8-ad2c-123a5c1adbbe'	System	04 Sep 2020 00:21:57
User entered '03 Sep 2020 20:21'	System	04 Sep 2020 00:21:57

FDA-CBER-2022-1614-3119714

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119715

US3742137
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119716

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:27', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1e2cfccd-8474-4e64-bb2c-fca7a22cfb2b'	System	28 Aug 2020 18:16:48
User entered 'None (0)'	System	28 Aug 2020 18:16:48

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:28', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1e2cfccd-8474-4e64-bb2c-fca7a22cfb2b'	System	28 Aug 2020 18:16:48
User entered 'None (0)'	System	28 Aug 2020 18:16:48

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:31', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1e2cfccd-8474-4e64-bb2c-fca7a22cfb2b'	System	28 Aug 2020 18:16:48
User entered 'None (0)'	System	28 Aug 2020 18:16:48

FDA-CBER-2022-1614-3119720

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:34', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1e2cfccd-8474-4e64-bb2c-fca7a22cfb2b'	System	28 Aug 2020 18:16:48
User entered 'None (0)'	System	28 Aug 2020 18:16:48

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:35', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1e2cfccd-8474-4e64-bb2c-fca7a22cfb2b'	System	28 Aug 2020 18:16:48
User entered 'None (0)'	System	28 Aug 2020 18:16:48

FDA-CBER-2022-1614-3119722

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:37', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1e2cfccd-8474-4e64-bb2c-fca7a22cfb2b'	System	28 Aug 2020 18:16:48
User entered 'None (0)'	System	28 Aug 2020 18:16:48

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:41', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1e2cfccd-8474-4e64-bb2c-fca7a22cfb2b'	System	28 Aug 2020 18:16:48
User entered 'No (N)'	System	28 Aug 2020 18:16:48

FDA-CBER-2022-1614-3119724

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T14:16:43', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1e2cfccd-8474-4e64-bb2c-fca7a22cfb2b'	System	28 Aug 2020 18:16:48
User entered '28 Aug 2020 14:16'	System	28 Aug 2020 18:16:48

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Aug 2020 14:01'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119726

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Aug 2020 16:31'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119727

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:24:13', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2180cdf9-e64f-4559-b3b4-4018c5205605'	System	29 Aug 2020 01:24:54
User entered 'No interference with activity (1)'	System	29 Aug 2020 01:24:54

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:24:19', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2180cdf9-e64f-4559-b3b4-4018c5205605'	System	29 Aug 2020 01:24:54
User entered 'Some interference with activity (2)'	System	29 Aug 2020 01:24:54

FDA-CBER-2022-1614-3119730

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:24:25', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2180cdf9-e64f-4559-b3b4-4018c5205605'	System	29 Aug 2020 01:24:54
User entered 'None (0)'	System	29 Aug 2020 01:24:54

FDA-CBER-2022-1614-3119731

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:24:28', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2180cdf9-e64f-4559-b3b4-4018c5205605'	System	29 Aug 2020 01:24:54
User entered 'None (0)'	System	29 Aug 2020 01:24:54

FDA-CBER-2022-1614-3119732

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:24:37', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2180cdf9-e64f-4559-b3b4-4018c5205605'	System	29 Aug 2020 01:24:54
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	29 Aug 2020 01:24:54

FDA-CBER-2022-1614-3119733

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:24:41', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2180cdf9-e64f-4559-b3b4-4018c5205605'	System	29 Aug 2020 01:24:54
User entered 'None (0)'	System	29 Aug 2020 01:24:54

FDA-CBER-2022-1614-3119734

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:24:46', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2180cdf9-e64f-4559-b3b4-4018c5205605'	System	29 Aug 2020 01:24:54
User entered 'No (N)'	System	29 Aug 2020 01:24:54

FDA-CBER-2022-1614-3119735

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-28T21:24:49', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2180cdf9-e64f-4559-b3b4-4018c5205605'	System	29 Aug 2020 01:24:54
User entered '28 Aug 2020 21:24'	System	29 Aug 2020 01:24:54

FDA-CBER-2022-1614-3119736

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Aug 2020 17:26'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119737

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119738

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 2'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119739

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:43:05', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'cc51219d-f7ee-4107-8bd1-c7dd4f7fc45a'	System	29 Aug 2020 17:43:31
User entered 'None (0)'	System	29 Aug 2020 17:43:31

FDA-CBER-2022-1614-3119740

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:43:08', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'cc51219d-f7ee-4107-8bd1-c7dd4f7fc45a'	System	29 Aug 2020 17:43:31
User entered 'No interference with activity (1)'	System	29 Aug 2020 17:43:31

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:43:14', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'cc51219d-f7ee-4107-8bd1-c7dd4f7fc45a'	System	29 Aug 2020 17:43:31
User entered 'None (0)'	System	29 Aug 2020 17:43:31

FDA-CBER-2022-1614-3119742

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:43:16', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'cc51219d-f7ee-4107-8bd1-c7dd4f7fc45a'	System	29 Aug 2020 17:43:31
User entered 'None (0)'	System	29 Aug 2020 17:43:31

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:43:19', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'cc51219d-f7ee-4107-8bd1-c7dd4f7fc45a'	System	29 Aug 2020 17:43:31
User entered 'None (0)'	System	29 Aug 2020 17:43:31

FDA-CBER-2022-1614-3119744

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:43:22', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'cc51219d-f7ee-4107-8bd1-c7dd4f7fc45a'	System	29 Aug 2020 17:43:31
User entered 'None (0)'	System	29 Aug 2020 17:43:31

FDA-CBER-2022-1614-3119745

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:43:27', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'cc51219d-f7ee-4107-8bd1-c7dd4f7fc45a'	System	29 Aug 2020 17:43:31
User entered 'No (N)'	System	29 Aug 2020 17:43:31

FDA-CBER-2022-1614-3119746

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-29T13:43:29', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'cc51219d-f7ee-4107-8bd1-c7dd4f7fc45a'	System	29 Aug 2020 17:43:31
User entered '29 Aug 2020 13:43'	System	29 Aug 2020 17:43:31

FDA-CBER-2022-1614-3119747

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119748

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119749

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 3'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119750

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:24:27', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9b6215a0-edf0-4415-bdd5-1b3d3b647b9e'	System	30 Aug 2020 17:24:52
User entered 'No interference with activity (1)'	System	30 Aug 2020 17:24:52

FDA-CBER-2022-1614-3119751

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:24:32', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9b6215a0-edf0-4415-bdd5-1b3d3b647b9e'	System	30 Aug 2020 17:24:52
User entered 'No interference with activity (1)'	System	30 Aug 2020 17:24:52

FDA-CBER-2022-1614-3119752

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:24:37', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9b6215a0-edf0-4415-bdd5-1b3d3b647b9e'	System	30 Aug 2020 17:24:52
User entered 'No interference with activity (1)'	System	30 Aug 2020 17:24:52

FDA-CBER-2022-1614-3119753

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:24:39', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9b6215a0-edf0-4415-bdd5-1b3d3b647b9e'	System	30 Aug 2020 17:24:52
User entered 'None (0)'	System	30 Aug 2020 17:24:52

FDA-CBER-2022-1614-3119754

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:24:42', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9b6215a0-edf0-4415-bdd5-1b3d3b647b9e'	System	30 Aug 2020 17:24:52
User entered 'None (0)'	System	30 Aug 2020 17:24:52

FDA-CBER-2022-1614-3119755

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:24:44', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9b6215a0-edf0-4415-bdd5-1b3d3b647b9e'	System	30 Aug 2020 17:24:52
User entered 'None (0)'	System	30 Aug 2020 17:24:52

FDA-CBER-2022-1614-3119756

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:24:48', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9b6215a0-edf0-4415-bdd5-1b3d3b647b9e'	System	30 Aug 2020 17:24:52
User entered 'No (N)'	System	30 Aug 2020 17:24:52

FDA-CBER-2022-1614-3119757

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-30T13:24:51', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9b6215a0-edf0-4415-bdd5-1b3d3b647b9e'	System	30 Aug 2020 17:24:52
User entered '30 Aug 2020 13:24'	System	30 Aug 2020 17:24:52

FDA-CBER-2022-1614-3119758

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119760

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 4'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119761

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:28', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e6593c19-8e6a-4730-877b-831b47c7a3a7'	System	31 Aug 2020 22:25:48
User entered 'None (0)'	System	31 Aug 2020 22:25:48

FDA-CBER-2022-1614-3119762

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:30', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e6593c19-8e6a-4730-877b-831b47c7a3a7'	System	31 Aug 2020 22:25:48
User entered 'No interference with activity (1)'	System	31 Aug 2020 22:25:48

FDA-CBER-2022-1614-3119763

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:34', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e6593c19-8e6a-4730-877b-831b47c7a3a7'	System	31 Aug 2020 22:25:48
User entered 'None (0)'	System	31 Aug 2020 22:25:48

FDA-CBER-2022-1614-3119764

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:36', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e6593c19-8e6a-4730-877b-831b47c7a3a7'	System	31 Aug 2020 22:25:48
User entered 'None (0)'	System	31 Aug 2020 22:25:48

FDA-CBER-2022-1614-3119765

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:38', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e6593c19-8e6a-4730-877b-831b47c7a3a7'	System	31 Aug 2020 22:25:48
User entered 'None (0)'	System	31 Aug 2020 22:25:48

FDA-CBER-2022-1614-3119766

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:40', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e6593c19-8e6a-4730-877b-831b47c7a3a7'	System	31 Aug 2020 22:25:48
User entered 'None (0)'	System	31 Aug 2020 22:25:48

FDA-CBER-2022-1614-3119767

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:43', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e6593c19-8e6a-4730-877b-831b47c7a3a7'	System	31 Aug 2020 22:25:48
User entered 'No (N)'	System	31 Aug 2020 22:25:48

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-08-31T18:25:45', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e6593c19-8e6a-4730-877b-831b47c7a3a7'	System	31 Aug 2020 22:25:48
User entered '31 Aug 2020 18:25'	System	31 Aug 2020 22:25:48

FDA-CBER-2022-1614-3119769

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119770

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119771

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 5'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119772

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:22', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '891b84c1-dc56-4edf-a3d7-27a45681d77d'	System	01 Sep 2020 22:37:47
User entered 'None (0)'	System	01 Sep 2020 22:37:47

FDA-CBER-2022-1614-3119773

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:25', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '891b84c1-dc56-4edf-a3d7-27a45681d77d'	System	01 Sep 2020 22:37:47
User entered 'No interference with activity (1)'	System	01 Sep 2020 22:37:47

FDA-CBER-2022-1614-3119774

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:28', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '891b84c1-dc56-4edf-a3d7-27a45681d77d'	System	01 Sep 2020 22:37:47
User entered 'None (0)'	System	01 Sep 2020 22:37:47

FDA-CBER-2022-1614-3119775

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:32', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '891b84c1-dc56-4edf-a3d7-27a45681d77d'	System	01 Sep 2020 22:37:47
User entered 'No interference with activity (1)'	System	01 Sep 2020 22:37:47

FDA-CBER-2022-1614-3119776

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:35', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '891b84c1-dc56-4edf-a3d7-27a45681d77d'	System	01 Sep 2020 22:37:47
User entered 'None (0)'	System	01 Sep 2020 22:37:47

FDA-CBER-2022-1614-3119777

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:37', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '891b84c1-dc56-4edf-a3d7-27a45681d77d'	System	01 Sep 2020 22:37:47
User entered 'None (0)'	System	01 Sep 2020 22:37:47

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:42', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '891b84c1-dc56-4edf-a3d7-27a45681d77d'	System	01 Sep 2020 22:37:47
User entered 'No (N)'	System	01 Sep 2020 22:37:47

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-01T18:37:44', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '891b84c1-dc56-4edf-a3d7-27a45681d77d'	System	01 Sep 2020 22:37:47
User entered '01 Sep 2020 18:37'	System	01 Sep 2020 22:37:47

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119782

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 6'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:14', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd4591bbd-39dc-4e7e-be00-3a7f73dfd57f'	System	02 Sep 2020 21:02:41
User entered 'No interference with activity (1)'	System	02 Sep 2020 21:02:41

FDA-CBER-2022-1614-3119784

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:17', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd4591bbd-39dc-4e7e-be00-3a7f73dfd57f'	System	02 Sep 2020 21:02:41
User entered 'No interference with activity (1)'	System	02 Sep 2020 21:02:41

FDA-CBER-2022-1614-3119785

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:19', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd4591bbd-39dc-4e7e-be00-3a7f73dfd57f'	System	02 Sep 2020 21:02:41
User entered 'None (0)'	System	02 Sep 2020 21:02:41

FDA-CBER-2022-1614-3119786

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:20', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd4591bbd-39dc-4e7e-be00-3a7f73dfd57f'	System	02 Sep 2020 21:02:41
User entered 'None (0)'	System	02 Sep 2020 21:02:41

FDA-CBER-2022-1614-3119787

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:22', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd4591bbd-39dc-4e7e-be00-3a7f73dfd57f'	System	02 Sep 2020 21:02:41
User entered 'None (0)'	System	02 Sep 2020 21:02:41

FDA-CBER-2022-1614-3119788

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:25', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd4591bbd-39dc-4e7e-be00-3a7f73dfd57f'	System	02 Sep 2020 21:02:41
User entered 'None (0)'	System	02 Sep 2020 21:02:41

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:30', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd4591bbd-39dc-4e7e-be00-3a7f73dfd57f'	System	02 Sep 2020 21:02:41
User entered 'No (N)'	System	02 Sep 2020 21:02:41

FDA-CBER-2022-1614-3119790

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-02T17:02:33', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd4591bbd-39dc-4e7e-be00-3a7f73dfd57f'	System	02 Sep 2020 21:02:41
User entered '02 Sep 2020 17:02'	System	02 Sep 2020 21:02:41

FDA-CBER-2022-1614-3119791

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119792

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119793

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 7'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119794

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:21:57', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '790b90d2-9388-49e3-89e6-d0ca48fe39b6'	System	04 Sep 2020 00:22:17
User entered 'None (0)'	System	04 Sep 2020 00:22:17

FDA-CBER-2022-1614-3119795

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:21:59', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '790b90d2-9388-49e3-89e6-d0ca48fe39b6'	System	04 Sep 2020 00:22:17
User entered 'None (0)'	System	04 Sep 2020 00:22:17

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:22:02', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '790b90d2-9388-49e3-89e6-d0ca48fe39b6'	System	04 Sep 2020 00:22:17
User entered 'None (0)'	System	04 Sep 2020 00:22:17

FDA-CBER-2022-1614-3119797

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:22:05', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '790b90d2-9388-49e3-89e6-d0ca48fe39b6'	System	04 Sep 2020 00:22:17
User entered 'None (0)'	System	04 Sep 2020 00:22:17

FDA-CBER-2022-1614-3119798

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:22:07', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '790b90d2-9388-49e3-89e6-d0ca48fe39b6'	System	04 Sep 2020 00:22:17
User entered 'None (0)'	System	04 Sep 2020 00:22:17

FDA-CBER-2022-1614-3119799

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:22:09', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '790b90d2-9388-49e3-89e6-d0ca48fe39b6'	System	04 Sep 2020 00:22:17
User entered 'None (0)'	System	04 Sep 2020 00:22:17

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:22:12', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '790b90d2-9388-49e3-89e6-d0ca48fe39b6'	System	04 Sep 2020 00:22:17
User entered 'No (N)'	System	04 Sep 2020 00:22:17

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-03T20:22:15', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '790b90d2-9388-49e3-89e6-d0ca48fe39b6'	System	04 Sep 2020 00:22:17
User entered '03 Sep 2020 20:22'	System	04 Sep 2020 00:22:17

FDA-CBER-2022-1614-3119802

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 18:01:54

US3742137
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 18:01:54

FDA-CBER-2022-1614-3119804

US3742137
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:19:20
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	04 Sep 2020 23:07:26

US3742137
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:19:20
User entered '4 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	04 Sep 2020 23:07:26

US3742137
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:19:20
User entered 'Contact Made (CONTACT MADE)'	Faith Pa'ahana-Brown (b) (4)	04 Sep 2020 23:07:26

US3742137
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:19:20
User entered empty.	Faith Pa'ahana-Brown (b) (4)	04 Sep 2020 23:07:26

FDA-CBER-2022-1614-3119808

US3742137
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:19:56
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	04 Sep 2020 23:07:33

US3742137
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '1'	System	04 Sep 2020 23:07:33

US3742137
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:20:28
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 23:08:34

US3742137
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:20:28
User entered '11 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 23:08:34

US3742137
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:20:28
User entered 'Contact Made (CONTACT MADE)'	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 23:08:34

US3742137
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:20:28
User entered empty.	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 23:08:34

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US3742137
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:20:34
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 23:08:38

US3742137
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '1'	System	11 Sep 2020 23:08:38

US3742137
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:21:11
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 19:14:32

US3742137
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:21:11
User entered '18 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 19:14:32

US3742137
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:21:11
User entered 'Contact Made (CONTACT MADE)'	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 19:14:32

US3742137
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:21:11
User entered empty.	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 19:14:32

FDA-CBER-2022-1614-3119820

US3742137
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:21:16
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 19:14:37

US3742137
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '1'	System	18 Sep 2020 19:14:37

US3742137
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:41:47

US3742137
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:17
User entered '25 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 12:41:47

FDA-CBER-2022-1614-3119824

US3742137
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Oct 2020 12:41:47

FDA-CBER-2022-1614-3119825

US3742137
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'VISIT2'	System	06 Oct 2020 12:41:47

FDA-CBER-2022-1614-3119826

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '25 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '11:10'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119830

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '25 Sep 2020 11:10'	System	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119831

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '098.4' F	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119832

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 12:45:17

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '085'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119835

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'bpm'	System	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119836

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '18'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119837

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'breaths/min'	System	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119838

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '142'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119839

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'mmHg'	System	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119840

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '083'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119841

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'mmHg'	System	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119842

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119843

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119844

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '25 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119845

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '12:34'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119846

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '25 Sep 2020 12:34'	System	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119847

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '098.6' F	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119848

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119849

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119850

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '081'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119851

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'bpm'	System	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119852

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '16'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119853

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'breaths/min'	System	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119854

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '137'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119855

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'mmHg'	System	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119856

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:02:55
User entered '082'	(b) (4), (b) (6)	06 Oct 2020 12:45:17

FDA-CBER-2022-1614-3119857

US3742137
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'mmHg'	System	06 Oct 2020 12:45:17

US3742137
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:34:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:43:27

FDA-CBER-2022-1614-3119859

US3742137
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:34:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:01
User entered '25 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 12:43:27

FDA-CBER-2022-1614-3119860

US3742137
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119861

US3742137
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:35
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119862

US3742137
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:35
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:05:47

US3742137
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 16:05:47

US3742137
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:35
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119865

US3742137
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:35
User entered '12:04'	(b) (4), (b) (6)	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119866

US3742137
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '25 Sep 2020 12:04'	System	25 Sep 2020 16:05:47

US3742137
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:35
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119868

US3742137
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:35
User entered 'ONCE'	System	25 Sep 2020 16:05:47

US3742137
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:34:30
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119870

US3742137
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:42:08

FDA-CBER-2022-1614-3119871

US3742137
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:41
User entered '25 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 12:42:08

FDA-CBER-2022-1614-3119872

US3742137
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:41
User entered '11:26'	(b) (4), (b) (6)	06 Oct 2020 12:42:08

US3742137
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '25 Sep 2020 11:26'	System	06 Oct 2020 12:42:08

FDA-CBER-2022-1614-3119874

US3742137
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:34:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:46
User entered '25 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 12:42:26

FDA-CBER-2022-1614-3119875

US3742137
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:34:30
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Oct 2020 12:42:26

FDA-CBER-2022-1614-3119876

US3742137
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:34:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:42:26

US3742137
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:34:30
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:46
User entered '11:25'	(b) (4), (b) (6)	06 Oct 2020 12:42:26

FDA-CBER-2022-1614-3119878

US3742137
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:34:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '25 Sep 2020 11:25'	System	06 Oct 2020 12:42:26

FDA-CBER-2022-1614-3119879

US3742137
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:34:30
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Oct 2020 12:42:26

US3742137
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:34:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:46
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 12:42:26

US3742137
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:34:30
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:46
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 12:42:26

US3742137
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:34:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered empty.	System	06 Oct 2020 12:42:26

US3742137
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:45:22

FDA-CBER-2022-1614-3119884

US3742137
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '1'	System	06 Oct 2020 12:45:22

FDA-CBER-2022-1614-3119885

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119886

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:36:37', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0a6d316c-9941-444d-8a9f-7d69232335a3'	System	25 Sep 2020 16:36:50
User entered 'Yes (Y)'	System	25 Sep 2020 16:36:50

FDA-CBER-2022-1614-3119887

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:36:41', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0a6d316c-9941-444d-8a9f-7d69232335a3'	System	25 Sep 2020 16:36:50
User entered '98.6'	System	25 Sep 2020 16:36:50

FDA-CBER-2022-1614-3119888

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:36:44', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0a6d316c-9941-444d-8a9f-7d69232335a3'	System	25 Sep 2020 16:36:50
User entered 'No (N)'	System	25 Sep 2020 16:36:50

FDA-CBER-2022-1614-3119889

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:36:47', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0a6d316c-9941-444d-8a9f-7d69232335a3'	System	25 Sep 2020 16:36:50
User entered '25 Sep 2020 12:36'	System	25 Sep 2020 16:36:50

FDA-CBER-2022-1614-3119890

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '25 Sep 2020 12:24'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119891

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '25 Sep 2020 14:54'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119892

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119893

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:21:26', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '369b88cf-7ee6-4f73-8af1-8151229fecec'	System	25 Sep 2020 23:21:48
User entered 'Yes (Y)'	System	25 Sep 2020 23:21:48

FDA-CBER-2022-1614-3119894

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:21:29', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '369b88cf-7ee6-4f73-8af1-8151229fecec'	System	25 Sep 2020 23:21:48
User entered '99.6'	System	25 Sep 2020 23:21:48

FDA-CBER-2022-1614-3119895

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:21:37', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '369b88cf-7ee6-4f73-8af1-8151229fecec'	System	25 Sep 2020 23:21:48
User entered 'Yes (Y)'	System	25 Sep 2020 23:21:48

FDA-CBER-2022-1614-3119896

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
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)	06 Oct 2020 08:23:07
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 'MEDICATION ADDED' (Site from System).	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:16
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	25 Sep 2020 23:21:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:21:43', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '369b88cf-7ee6-4f73-8af1-8151229fecec'	System	25 Sep 2020 23:21:48
User entered '1'	System	25 Sep 2020 23:21:48

FDA-CBER-2022-1614-3119897

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:21:43', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '369b88cf-7ee6-4f73-8af1-8151229fecec'	System	25 Sep 2020 23:21:48
User entered '0'	System	25 Sep 2020 23:21:48

FDA-CBER-2022-1614-3119898

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:21:46', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '369b88cf-7ee6-4f73-8af1-8151229fecec'	System	25 Sep 2020 23:21:48
User entered '25 Sep 2020 19:21'	System	25 Sep 2020 23:21:48

FDA-CBER-2022-1614-3119899

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '25 Sep 2020 15:49'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119900

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119901

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 2'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119902

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:02', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd5e2fb94-4cfc-45f1-a52c-cfc86cf3ddc7'	System	26 Sep 2020 23:35:23
User entered 'Yes (Y)'	System	26 Sep 2020 23:35:23

FDA-CBER-2022-1614-3119903

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:10', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd5e2fb94-4cfc-45f1-a52c-cfc86cf3ddc7'	System	26 Sep 2020 23:35:23
User entered '102.0'	System	26 Sep 2020 23:35:23

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:13', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd5e2fb94-4cfc-45f1-a52c-cfc86cf3ddc7'	System	26 Sep 2020 23:35:23
User entered 'Yes (Y)'	System	26 Sep 2020 23:35:23

FDA-CBER-2022-1614-3119905

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
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)	06 Oct 2020 08:26:05
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 'MEDICATION ADDED' (Site from System).	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:25
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	26 Sep 2020 23:35:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:18', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd5e2fb94-4cfc-45f1-a52c-cfc86cf3ddc7'	System	26 Sep 2020 23:35:23
User entered '1'	System	26 Sep 2020 23:35:23

FDA-CBER-2022-1614-3119906

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:18', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd5e2fb94-4cfc-45f1-a52c-cfc86cf3ddc7'	System	26 Sep 2020 23:35:23
User entered '0'	System	26 Sep 2020 23:35:23

FDA-CBER-2022-1614-3119907

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:20', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd5e2fb94-4cfc-45f1-a52c-cfc86cf3ddc7'	System	26 Sep 2020 23:35:23
User entered '26 Sep 2020 19:35'	System	26 Sep 2020 23:35:23

FDA-CBER-2022-1614-3119908

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119909

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119910

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 3'	System	25 Sep 2020 16:05:47

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:41:36', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2b0a34d7-49c2-4585-b072-fea7b0ea86b7'	System	27 Sep 2020 22:41:56
User entered 'Yes (Y)'	System	27 Sep 2020 22:41:56

FDA-CBER-2022-1614-3119912

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:41:44', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2b0a34d7-49c2-4585-b072-fea7b0ea86b7'	System	27 Sep 2020 22:41:56
User entered '100.4'	System	27 Sep 2020 22:41:56

FDA-CBER-2022-1614-3119913

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:41:47', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2b0a34d7-49c2-4585-b072-fea7b0ea86b7'	System	27 Sep 2020 22:41:56
User entered 'Yes (Y)'	System	27 Sep 2020 22:41:56

FDA-CBER-2022-1614-3119914

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
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)	06 Oct 2020 08:27:04
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 'MEDICATION ADDED' (Site from System).	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:34
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	27 Sep 2020 22:41:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:41:50', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2b0a34d7-49c2-4585-b072-fea7b0ea86b7'	System	27 Sep 2020 22:41:56
User entered '1'	System	27 Sep 2020 22:41:56

FDA-CBER-2022-1614-3119915

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:41:50', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2b0a34d7-49c2-4585-b072-fea7b0ea86b7'	System	27 Sep 2020 22:41:56
User entered '0'	System	27 Sep 2020 22:41:56

FDA-CBER-2022-1614-3119916

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:41:52', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2b0a34d7-49c2-4585-b072-fea7b0ea86b7'	System	27 Sep 2020 22:41:56
User entered '27 Sep 2020 18:41'	System	27 Sep 2020 22:41:56

FDA-CBER-2022-1614-3119917

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119918

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119919

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 4'	System	25 Sep 2020 16:05:47

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:06:41', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'a2461518-6550-4858-a84d-47fbb7f00aad'	System	29 Sep 2020 01:07:04
User entered 'Yes (Y)'	System	29 Sep 2020 01:07:04

FDA-CBER-2022-1614-3119921

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:06:51', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'a2461518-6550-4858-a84d-47fbb7f00aad'	System	29 Sep 2020 01:07:04
User entered '99.2'	System	29 Sep 2020 01:07:04

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:06:59', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'a2461518-6550-4858-a84d-47fbb7f00aad'	System	29 Sep 2020 01:07:04
User entered 'No (N)'	System	29 Sep 2020 01:07:04

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:01', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'a2461518-6550-4858-a84d-47fbb7f00aad'	System	29 Sep 2020 01:07:04
User entered '28 Sep 2020 21:07'	System	29 Sep 2020 01:07:04

FDA-CBER-2022-1614-3119924

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119925

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119926

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 5'	System	25 Sep 2020 16:05:47

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:39:57', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '450c569f-6ac7-479a-a465-a9911083db65'	System	30 Sep 2020 02:40:12
User entered 'Yes (Y)'	System	30 Sep 2020 02:40:12

FDA-CBER-2022-1614-3119928

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:40:05', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '450c569f-6ac7-479a-a465-a9911083db65'	System	30 Sep 2020 02:40:12
User entered '98.9'	System	30 Sep 2020 02:40:12

FDA-CBER-2022-1614-3119929

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:40:08', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '450c569f-6ac7-479a-a465-a9911083db65'	System	30 Sep 2020 02:40:12
User entered 'No (N)'	System	30 Sep 2020 02:40:12

FDA-CBER-2022-1614-3119930

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:40:10', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '450c569f-6ac7-479a-a465-a9911083db65'	System	30 Sep 2020 02:40:12
User entered '29 Sep 2020 22:40'	System	30 Sep 2020 02:40:12

FDA-CBER-2022-1614-3119931

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119932

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119933

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 6'	System	25 Sep 2020 16:05:47

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:22', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '3f9a2660-bf1b-4014-a875-e59c21d8d95d'	System	01 Oct 2020 02:53:35
User entered 'Yes (Y)'	System	01 Oct 2020 02:53:35

FDA-CBER-2022-1614-3119935

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:26', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '3f9a2660-bf1b-4014-a875-e59c21d8d95d'	System	01 Oct 2020 02:53:35
User entered '98.9'	System	01 Oct 2020 02:53:35

FDA-CBER-2022-1614-3119936

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:28', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '3f9a2660-bf1b-4014-a875-e59c21d8d95d'	System	01 Oct 2020 02:53:35
User entered 'No (N)'	System	01 Oct 2020 02:53:35

FDA-CBER-2022-1614-3119937

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:30', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '3f9a2660-bf1b-4014-a875-e59c21d8d95d'	System	01 Oct 2020 02:53:35
User entered '30 Sep 2020 22:53'	System	01 Oct 2020 02:53:35

FDA-CBER-2022-1614-3119938

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119939

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119940

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 7'	System	25 Sep 2020 16:05:47

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:03:42', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'c6690241-a91c-49bd-b844-8a6634ba5b45'	System	01 Oct 2020 22:03:59
User entered 'Yes (Y)'	System	01 Oct 2020 22:03:59

FDA-CBER-2022-1614-3119942

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:03:46', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'c6690241-a91c-49bd-b844-8a6634ba5b45'	System	01 Oct 2020 22:03:59
User entered '99.6'	System	01 Oct 2020 22:03:59

FDA-CBER-2022-1614-3119943

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:03:49', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'c6690241-a91c-49bd-b844-8a6634ba5b45'	System	01 Oct 2020 22:03:59
User entered 'No (N)'	System	01 Oct 2020 22:03:59

FDA-CBER-2022-1614-3119944

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:03:56', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'c6690241-a91c-49bd-b844-8a6634ba5b45'	System	01 Oct 2020 22:03:59
User entered '01 Oct 2020 18:03'	System	01 Oct 2020 22:03:59

FDA-CBER-2022-1614-3119945

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119946

US3742137
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119947

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119948

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:37:17', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '03a48ff8-36b9-4053-b863-c19f6e109a70'	System	25 Sep 2020 16:37:45
User entered 'None (1)'	System	25 Sep 2020 16:37:45

FDA-CBER-2022-1614-3119949

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:37:27', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '03a48ff8-36b9-4053-b863-c19f6e109a70'	System	25 Sep 2020 16:37:45
User entered 'No (N)'	System	25 Sep 2020 16:37:45

FDA-CBER-2022-1614-3119950

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:37:35', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '03a48ff8-36b9-4053-b863-c19f6e109a70'	System	25 Sep 2020 16:37:45
User entered 'No (N)'	System	25 Sep 2020 16:37:45

FDA-CBER-2022-1614-3119951

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:37:40', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '03a48ff8-36b9-4053-b863-c19f6e109a70'	System	25 Sep 2020 16:37:45
User entered 'None (1)'	System	25 Sep 2020 16:37:45

FDA-CBER-2022-1614-3119952

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:37:44', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '03a48ff8-36b9-4053-b863-c19f6e109a70'	System	25 Sep 2020 16:37:45
User entered '25 Sep 2020 12:37'	System	25 Sep 2020 16:37:45

FDA-CBER-2022-1614-3119953

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '25 Sep 2020 12:24'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119954

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '25 Sep 2020 14:54'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119955

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119956

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:22:22', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '65a5532a-c16b-47a0-aecf-b31f1d25c506'	System	25 Sep 2020 23:22:45
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	25 Sep 2020 23:22:45

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:22:32', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '65a5532a-c16b-47a0-aecf-b31f1d25c506'	System	25 Sep 2020 23:22:45
User entered 'No (N)'	System	25 Sep 2020 23:22:45

FDA-CBER-2022-1614-3119958

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:22:35', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '65a5532a-c16b-47a0-aecf-b31f1d25c506'	System	25 Sep 2020 23:22:45
User entered 'No (N)'	System	25 Sep 2020 23:22:45

FDA-CBER-2022-1614-3119959

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:22:41', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '65a5532a-c16b-47a0-aecf-b31f1d25c506'	System	25 Sep 2020 23:22:45
User entered 'None (1)'	System	25 Sep 2020 23:22:45

FDA-CBER-2022-1614-3119960

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:22:43', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '65a5532a-c16b-47a0-aecf-b31f1d25c506'	System	25 Sep 2020 23:22:45
User entered '25 Sep 2020 19:22'	System	25 Sep 2020 23:22:45

FDA-CBER-2022-1614-3119961

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '25 Sep 2020 15:49'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119962

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119963

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 2'	System	25 Sep 2020 16:05:47

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:27', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '8be4751f-244b-464a-9a8a-9014732e3709'	System	26 Sep 2020 23:35:53
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	26 Sep 2020 23:35:53

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:30', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '8be4751f-244b-464a-9a8a-9014732e3709'	System	26 Sep 2020 23:35:53
User entered 'Yes (Y)'	System	26 Sep 2020 23:35:53

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:34', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '8be4751f-244b-464a-9a8a-9014732e3709'	System	26 Sep 2020 23:35:53
User entered '3'	System	26 Sep 2020 23:35:53

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:40', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '8be4751f-244b-464a-9a8a-9014732e3709'	System	26 Sep 2020 23:35:53
User entered 'Yes (Y)'	System	26 Sep 2020 23:35:53

FDA-CBER-2022-1614-3119968

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:45', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '8be4751f-244b-464a-9a8a-9014732e3709'	System	26 Sep 2020 23:35:53
User entered '2'	System	26 Sep 2020 23:35:53

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:48', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '8be4751f-244b-464a-9a8a-9014732e3709'	System	26 Sep 2020 23:35:53
User entered 'None (1)'	System	26 Sep 2020 23:35:53

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:50', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '8be4751f-244b-464a-9a8a-9014732e3709'	System	26 Sep 2020 23:35:53
User entered '26 Sep 2020 19:35'	System	26 Sep 2020 23:35:53

FDA-CBER-2022-1614-3119971

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119972

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119973

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 3'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119974

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '59cb89af-4cca-48b9-beb5-961b8369dd17'	System	27 Sep 2020 22:42:25
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	27 Sep 2020 22:42:25

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:03', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '59cb89af-4cca-48b9-beb5-961b8369dd17'	System	27 Sep 2020 22:42:25
User entered 'Yes (Y)'	System	27 Sep 2020 22:42:25

FDA-CBER-2022-1614-3119976

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:08', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '59cb89af-4cca-48b9-beb5-961b8369dd17'	System	27 Sep 2020 22:42:25
User entered '115'	System	27 Sep 2020 22:42:25

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:10', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '59cb89af-4cca-48b9-beb5-961b8369dd17'	System	27 Sep 2020 22:42:25
User entered 'Yes (Y)'	System	27 Sep 2020 22:42:25

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:17', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '59cb89af-4cca-48b9-beb5-961b8369dd17'	System	27 Sep 2020 22:42:25
User entered '110'	System	27 Sep 2020 22:42:25

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:21', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '59cb89af-4cca-48b9-beb5-961b8369dd17'	System	27 Sep 2020 22:42:25
User entered 'None (1)'	System	27 Sep 2020 22:42:25

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:23', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '59cb89af-4cca-48b9-beb5-961b8369dd17'	System	27 Sep 2020 22:42:25
User entered '27 Sep 2020 18:42'	System	27 Sep 2020 22:42:25

FDA-CBER-2022-1614-3119981

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119982

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119983

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 4'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119984

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:06', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2e5f0232-f998-453d-ae16-4731f1c68821'	System	29 Sep 2020 01:07:34
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 01:07:34

FDA-CBER-2022-1614-3119985

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:09', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2e5f0232-f998-453d-ae16-4731f1c68821'	System	29 Sep 2020 01:07:34
User entered 'Yes (Y)'	System	29 Sep 2020 01:07:34

FDA-CBER-2022-1614-3119986

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:19', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2e5f0232-f998-453d-ae16-4731f1c68821'	System	29 Sep 2020 01:07:34
User entered '120'	System	29 Sep 2020 01:07:34

FDA-CBER-2022-1614-3119987

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:23', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2e5f0232-f998-453d-ae16-4731f1c68821'	System	29 Sep 2020 01:07:34
User entered 'Yes (Y)'	System	29 Sep 2020 01:07:34

FDA-CBER-2022-1614-3119988

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:27', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2e5f0232-f998-453d-ae16-4731f1c68821'	System	29 Sep 2020 01:07:34
User entered '120'	System	29 Sep 2020 01:07:34

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:30', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2e5f0232-f998-453d-ae16-4731f1c68821'	System	29 Sep 2020 01:07:34
User entered 'None (1)'	System	29 Sep 2020 01:07:34

FDA-CBER-2022-1614-3119990

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:32', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2e5f0232-f998-453d-ae16-4731f1c68821'	System	29 Sep 2020 01:07:34
User entered '28 Sep 2020 21:07'	System	29 Sep 2020 01:07:34

FDA-CBER-2022-1614-3119991

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119992

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119993

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 5'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3119994

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:40:16', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ec03c620-78f4-4743-930d-b9c97380ecf6'	System	30 Sep 2020 02:41:04
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 02:41:04

FDA-CBER-2022-1614-3119995

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:40:20', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ec03c620-78f4-4743-930d-b9c97380ecf6'	System	30 Sep 2020 02:41:04
User entered 'Yes (Y)'	System	30 Sep 2020 02:41:04

FDA-CBER-2022-1614-3119996

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:40:47', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ec03c620-78f4-4743-930d-b9c97380ecf6'	System	30 Sep 2020 02:41:04
User entered '70'	System	30 Sep 2020 02:41:04

FDA-CBER-2022-1614-3119997

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:40:51', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ec03c620-78f4-4743-930d-b9c97380ecf6'	System	30 Sep 2020 02:41:04
User entered 'Yes (Y)'	System	30 Sep 2020 02:41:04

FDA-CBER-2022-1614-3119998

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:40:55', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ec03c620-78f4-4743-930d-b9c97380ecf6'	System	30 Sep 2020 02:41:04
User entered '70'	System	30 Sep 2020 02:41:04

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:40:58', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ec03c620-78f4-4743-930d-b9c97380ecf6'	System	30 Sep 2020 02:41:04
User entered 'None (1)'	System	30 Sep 2020 02:41:04

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:41:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ec03c620-78f4-4743-930d-b9c97380ecf6'	System	30 Sep 2020 02:41:04
User entered '29 Sep 2020 22:41'	System	30 Sep 2020 02:41:04

FDA-CBER-2022-1614-3120001

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120002

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120003

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 6'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120004

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:39', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '179cf6ff-7022-4c53-8f7a-75108076ecb5'	System	01 Oct 2020 02:53:51
User entered 'None (1)'	System	01 Oct 2020 02:53:51

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:42', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '179cf6ff-7022-4c53-8f7a-75108076ecb5'	System	01 Oct 2020 02:53:51
User entered 'No (N)'	System	01 Oct 2020 02:53:51

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:44', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '179cf6ff-7022-4c53-8f7a-75108076ecb5'	System	01 Oct 2020 02:53:51
User entered 'No (N)'	System	01 Oct 2020 02:53:51

FDA-CBER-2022-1614-3120007

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:46', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '179cf6ff-7022-4c53-8f7a-75108076ecb5'	System	01 Oct 2020 02:53:51
User entered 'None (1)'	System	01 Oct 2020 02:53:51

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:48', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '179cf6ff-7022-4c53-8f7a-75108076ecb5'	System	01 Oct 2020 02:53:51
User entered '30 Sep 2020 22:53'	System	01 Oct 2020 02:53:51

FDA-CBER-2022-1614-3120009

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120010

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120011

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 7'	System	25 Sep 2020 16:05:47

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '86dc264e-ca7f-44bf-b1b5-3b7bb570aa41'	System	01 Oct 2020 22:04:16
User entered 'None (1)'	System	01 Oct 2020 22:04:16

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:03', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '86dc264e-ca7f-44bf-b1b5-3b7bb570aa41'	System	01 Oct 2020 22:04:16
User entered 'No (N)'	System	01 Oct 2020 22:04:16

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:09', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '86dc264e-ca7f-44bf-b1b5-3b7bb570aa41'	System	01 Oct 2020 22:04:16
User entered 'No (N)'	System	01 Oct 2020 22:04:16

FDA-CBER-2022-1614-3120015

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:12', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '86dc264e-ca7f-44bf-b1b5-3b7bb570aa41'	System	01 Oct 2020 22:04:16
User entered 'None (1)'	System	01 Oct 2020 22:04:16

FDA-CBER-2022-1614-3120016

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:14', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '86dc264e-ca7f-44bf-b1b5-3b7bb570aa41'	System	01 Oct 2020 22:04:16
User entered '01 Oct 2020 18:04'	System	01 Oct 2020 22:04:16

FDA-CBER-2022-1614-3120017

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120018

US3742137
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120019

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120020

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:37:48', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ebc72df9-0a71-4b26-8b18-25b6e6d31fe4'	System	25 Sep 2020 16:38:08
User entered 'None (0)'	System	25 Sep 2020 16:38:08

FDA-CBER-2022-1614-3120021

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:37:51', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ebc72df9-0a71-4b26-8b18-25b6e6d31fe4'	System	25 Sep 2020 16:38:08
User entered 'None (0)'	System	25 Sep 2020 16:38:08

FDA-CBER-2022-1614-3120022

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:37:54', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ebc72df9-0a71-4b26-8b18-25b6e6d31fe4'	System	25 Sep 2020 16:38:08
User entered 'None (0)'	System	25 Sep 2020 16:38:08

FDA-CBER-2022-1614-3120023

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:37:56', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ebc72df9-0a71-4b26-8b18-25b6e6d31fe4'	System	25 Sep 2020 16:38:08
User entered 'None (0)'	System	25 Sep 2020 16:38:08

FDA-CBER-2022-1614-3120024

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:37:59', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ebc72df9-0a71-4b26-8b18-25b6e6d31fe4'	System	25 Sep 2020 16:38:08
User entered 'None (0)'	System	25 Sep 2020 16:38:08

FDA-CBER-2022-1614-3120025

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:38:01', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ebc72df9-0a71-4b26-8b18-25b6e6d31fe4'	System	25 Sep 2020 16:38:08
User entered 'None (0)'	System	25 Sep 2020 16:38:08

FDA-CBER-2022-1614-3120026

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:38:05', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ebc72df9-0a71-4b26-8b18-25b6e6d31fe4'	System	25 Sep 2020 16:38:08
User entered 'No (N)'	System	25 Sep 2020 16:38:08

FDA-CBER-2022-1614-3120027

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T12:38:07', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ebc72df9-0a71-4b26-8b18-25b6e6d31fe4'	System	25 Sep 2020 16:38:08
User entered '25 Sep 2020 12:38'	System	25 Sep 2020 16:38:08

FDA-CBER-2022-1614-3120028

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '25 Sep 2020 12:24'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120029

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '25 Sep 2020 14:54'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120030

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120031

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:22:49', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e174dedd-dfe0-4f4a-b8d2-4dbea74ff6dc'	System	25 Sep 2020 23:23:23
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	25 Sep 2020 23:23:23

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:22:57', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e174dedd-dfe0-4f4a-b8d2-4dbea74ff6dc'	System	25 Sep 2020 23:23:23
User entered 'Some interference with activity (2)'	System	25 Sep 2020 23:23:23

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:23:02', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e174dedd-dfe0-4f4a-b8d2-4dbea74ff6dc'	System	25 Sep 2020 23:23:23
User entered 'Some interference with activity (2)'	System	25 Sep 2020 23:23:23

FDA-CBER-2022-1614-3120034

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:23:09', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e174dedd-dfe0-4f4a-b8d2-4dbea74ff6dc'	System	25 Sep 2020 23:23:23
User entered 'None (0)'	System	25 Sep 2020 23:23:23

FDA-CBER-2022-1614-3120035

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:23:11', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e174dedd-dfe0-4f4a-b8d2-4dbea74ff6dc'	System	25 Sep 2020 23:23:23
User entered 'None (0)'	System	25 Sep 2020 23:23:23

FDA-CBER-2022-1614-3120036

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:23:15', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e174dedd-dfe0-4f4a-b8d2-4dbea74ff6dc'	System	25 Sep 2020 23:23:23
User entered 'None (0)'	System	25 Sep 2020 23:23:23

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:23:19', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e174dedd-dfe0-4f4a-b8d2-4dbea74ff6dc'	System	25 Sep 2020 23:23:23
User entered 'No (N)'	System	25 Sep 2020 23:23:23

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-25T19:23:21', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e174dedd-dfe0-4f4a-b8d2-4dbea74ff6dc'	System	25 Sep 2020 23:23:23
User entered '25 Sep 2020 19:23'	System	25 Sep 2020 23:23:23

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '25 Sep 2020 15:49'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120040

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120041

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 2'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120042

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:35:58', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '89325505-80d9-4d63-9686-50b5b97cbba7'	System	26 Sep 2020 23:36:44
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	26 Sep 2020 23:36:44

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:36:06', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '89325505-80d9-4d63-9686-50b5b97cbba7'	System	26 Sep 2020 23:36:44
User entered 'Significant; prevents daily activity (3)'	System	26 Sep 2020 23:36:44

FDA-CBER-2022-1614-3120044

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:36:09', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '89325505-80d9-4d63-9686-50b5b97cbba7'	System	26 Sep 2020 23:36:44
User entered 'Some interference with activity (2)'	System	26 Sep 2020 23:36:44

FDA-CBER-2022-1614-3120045

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:36:13', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '89325505-80d9-4d63-9686-50b5b97cbba7'	System	26 Sep 2020 23:36:44
User entered 'No interference with activity (1)'	System	26 Sep 2020 23:36:44

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:36:17', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '89325505-80d9-4d63-9686-50b5b97cbba7'	System	26 Sep 2020 23:36:44
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	26 Sep 2020 23:36:44

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:36:22', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '89325505-80d9-4d63-9686-50b5b97cbba7'	System	26 Sep 2020 23:36:44
User entered 'Some interference with activity not requiring medical attention (2)'	System	26 Sep 2020 23:36:44

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:36:41', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '89325505-80d9-4d63-9686-50b5b97cbba7'	System	26 Sep 2020 23:36:44
User entered 'No (N)'	System	26 Sep 2020 23:36:44

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-26T19:36:42', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '89325505-80d9-4d63-9686-50b5b97cbba7'	System	26 Sep 2020 23:36:44
User entered '26 Sep 2020 19:36'	System	26 Sep 2020 23:36:44

FDA-CBER-2022-1614-3120050

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120051

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120052

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 3'	System	25 Sep 2020 16:05:47

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:28', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9adc84f1-42b2-4126-920f-bb50f8220952'	System	27 Sep 2020 22:42:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	27 Sep 2020 22:42:52

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:32', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9adc84f1-42b2-4126-920f-bb50f8220952'	System	27 Sep 2020 22:42:52
User entered 'Some interference with activity (2)'	System	27 Sep 2020 22:42:52

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:36', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9adc84f1-42b2-4126-920f-bb50f8220952'	System	27 Sep 2020 22:42:52
User entered 'Some interference with activity (2)'	System	27 Sep 2020 22:42:52

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:39', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9adc84f1-42b2-4126-920f-bb50f8220952'	System	27 Sep 2020 22:42:52
User entered 'None (0)'	System	27 Sep 2020 22:42:52

FDA-CBER-2022-1614-3120057

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:41', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9adc84f1-42b2-4126-920f-bb50f8220952'	System	27 Sep 2020 22:42:52
User entered 'None (0)'	System	27 Sep 2020 22:42:52

FDA-CBER-2022-1614-3120058

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:44', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9adc84f1-42b2-4126-920f-bb50f8220952'	System	27 Sep 2020 22:42:52
User entered 'None (0)'	System	27 Sep 2020 22:42:52

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:47', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9adc84f1-42b2-4126-920f-bb50f8220952'	System	27 Sep 2020 22:42:52
User entered 'No (N)'	System	27 Sep 2020 22:42:52

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-27T18:42:49', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '9adc84f1-42b2-4126-920f-bb50f8220952'	System	27 Sep 2020 22:42:52
User entered '27 Sep 2020 18:42'	System	27 Sep 2020 22:42:52

FDA-CBER-2022-1614-3120061

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120062

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 4'	System	25 Sep 2020 16:05:47

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:35', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '103c1798-3015-4dc7-b9aa-8cfc986fe2c0'	System	29 Sep 2020 01:07:58
User entered 'No interference with activity (1)'	System	29 Sep 2020 01:07:58

FDA-CBER-2022-1614-3120065

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:38', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '103c1798-3015-4dc7-b9aa-8cfc986fe2c0'	System	29 Sep 2020 01:07:58
User entered 'No interference with activity (1)'	System	29 Sep 2020 01:07:58

FDA-CBER-2022-1614-3120066

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:43', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '103c1798-3015-4dc7-b9aa-8cfc986fe2c0'	System	29 Sep 2020 01:07:58
User entered 'No interference with activity (1)'	System	29 Sep 2020 01:07:58

FDA-CBER-2022-1614-3120067

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:45', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '103c1798-3015-4dc7-b9aa-8cfc986fe2c0'	System	29 Sep 2020 01:07:58
User entered 'None (0)'	System	29 Sep 2020 01:07:58

FDA-CBER-2022-1614-3120068

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:47', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '103c1798-3015-4dc7-b9aa-8cfc986fe2c0'	System	29 Sep 2020 01:07:58
User entered 'None (0)'	System	29 Sep 2020 01:07:58

FDA-CBER-2022-1614-3120069

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:49', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '103c1798-3015-4dc7-b9aa-8cfc986fe2c0'	System	29 Sep 2020 01:07:58
User entered 'None (0)'	System	29 Sep 2020 01:07:58

FDA-CBER-2022-1614-3120070

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:52', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '103c1798-3015-4dc7-b9aa-8cfc986fe2c0'	System	29 Sep 2020 01:07:58
User entered 'No (N)'	System	29 Sep 2020 01:07:58

FDA-CBER-2022-1614-3120071

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-28T21:07:53', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '103c1798-3015-4dc7-b9aa-8cfc986fe2c0'	System	29 Sep 2020 01:07:58
User entered '28 Sep 2020 21:07'	System	29 Sep 2020 01:07:58

FDA-CBER-2022-1614-3120072

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120073

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120074

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 5'	System	25 Sep 2020 16:05:47

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:41:07', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '90ba9829-9dba-40f7-8b49-4cc3928c6640'	System	30 Sep 2020 02:41:31
User entered 'None (0)'	System	30 Sep 2020 02:41:31

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:41:11', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '90ba9829-9dba-40f7-8b49-4cc3928c6640'	System	30 Sep 2020 02:41:31
User entered 'No interference with activity (1)'	System	30 Sep 2020 02:41:31

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:41:14', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '90ba9829-9dba-40f7-8b49-4cc3928c6640'	System	30 Sep 2020 02:41:31
User entered 'None (0)'	System	30 Sep 2020 02:41:31

FDA-CBER-2022-1614-3120078

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:41:17', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '90ba9829-9dba-40f7-8b49-4cc3928c6640'	System	30 Sep 2020 02:41:31
User entered 'None (0)'	System	30 Sep 2020 02:41:31

FDA-CBER-2022-1614-3120079

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:41:19', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '90ba9829-9dba-40f7-8b49-4cc3928c6640'	System	30 Sep 2020 02:41:31
User entered 'None (0)'	System	30 Sep 2020 02:41:31

FDA-CBER-2022-1614-3120080

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:41:22', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '90ba9829-9dba-40f7-8b49-4cc3928c6640'	System	30 Sep 2020 02:41:31
User entered 'None (0)'	System	30 Sep 2020 02:41:31

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:41:27', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '90ba9829-9dba-40f7-8b49-4cc3928c6640'	System	30 Sep 2020 02:41:31
User entered 'No (N)'	System	30 Sep 2020 02:41:31

FDA-CBER-2022-1614-3120082

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-29T22:41:29', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '90ba9829-9dba-40f7-8b49-4cc3928c6640'	System	30 Sep 2020 02:41:31
User entered '29 Sep 2020 22:41'	System	30 Sep 2020 02:41:31

FDA-CBER-2022-1614-3120083

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120085

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 6'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120086

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:51', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0ffb90ad-6ae8-4159-b5d1-df467eab1d42'	System	01 Oct 2020 02:54:09
User entered 'None (0)'	System	01 Oct 2020 02:54:09

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:54', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0ffb90ad-6ae8-4159-b5d1-df467eab1d42'	System	01 Oct 2020 02:54:09
User entered 'No interference with activity (1)'	System	01 Oct 2020 02:54:09

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:56', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0ffb90ad-6ae8-4159-b5d1-df467eab1d42'	System	01 Oct 2020 02:54:09
User entered 'None (0)'	System	01 Oct 2020 02:54:09

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:53:58', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0ffb90ad-6ae8-4159-b5d1-df467eab1d42'	System	01 Oct 2020 02:54:09
User entered 'None (0)'	System	01 Oct 2020 02:54:09

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:54:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0ffb90ad-6ae8-4159-b5d1-df467eab1d42'	System	01 Oct 2020 02:54:09
User entered 'None (0)'	System	01 Oct 2020 02:54:09

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:54:02', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0ffb90ad-6ae8-4159-b5d1-df467eab1d42'	System	01 Oct 2020 02:54:09
User entered 'None (0)'	System	01 Oct 2020 02:54:09

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:54:05', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0ffb90ad-6ae8-4159-b5d1-df467eab1d42'	System	01 Oct 2020 02:54:09
User entered 'No (N)'	System	01 Oct 2020 02:54:09

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-09-30T22:54:07', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0ffb90ad-6ae8-4159-b5d1-df467eab1d42'	System	01 Oct 2020 02:54:09
User entered '30 Sep 2020 22:54'	System	01 Oct 2020 02:54:09

FDA-CBER-2022-1614-3120094

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120095

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120096

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	25 Sep 2020 16:05:47
User entered 'Day 7'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120097

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:18', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '5bbe360b-2bd7-4c6b-a863-aaeafc4b2752'	System	01 Oct 2020 22:04:40
User entered 'No interference with activity (1)'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120098

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:20', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '5bbe360b-2bd7-4c6b-a863-aaeafc4b2752'	System	01 Oct 2020 22:04:40
User entered 'No interference with activity (1)'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120099

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:26', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '5bbe360b-2bd7-4c6b-a863-aaeafc4b2752'	System	01 Oct 2020 22:04:40
User entered 'No interference with activity (1)'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120100

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:28', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '5bbe360b-2bd7-4c6b-a863-aaeafc4b2752'	System	01 Oct 2020 22:04:40
User entered 'None (0)'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120101

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:30', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '5bbe360b-2bd7-4c6b-a863-aaeafc4b2752'	System	01 Oct 2020 22:04:40
User entered 'None (0)'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120102

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:34', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '5bbe360b-2bd7-4c6b-a863-aaeafc4b2752'	System	01 Oct 2020 22:04:40
User entered 'None (0)'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120103

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:37', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '5bbe360b-2bd7-4c6b-a863-aaeafc4b2752'	System	01 Oct 2020 22:04:40
User entered 'No (N)'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120104

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-01T18:04:38', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '5bbe360b-2bd7-4c6b-a863-aaeafc4b2752'	System	01 Oct 2020 22:04:40
User entered '01 Oct 2020 18:04'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120105

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120106

US3742137
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 16:05:47

FDA-CBER-2022-1614-3120107

US3742137
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	01 Oct 2020 22:04:40
User entered 'Day 8'	System	01 Oct 2020 22:04:40

US3742137
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 10 Jun 2021 09:34:30
Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-02T21:15:06', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '4b5f4288-251c-4e93-b09b-e6d33826063e'	System	03 Oct 2020 01:15:11
User entered 'No interference with activity (1)'	System	03 Oct 2020 01:15:11

FDA-CBER-2022-1614-3120109

US3742137
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-02T21:15:08', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '4b5f4288-251c-4e93-b09b-e6d33826063e'	System	03 Oct 2020 01:15:11
User entered '02 Oct 2020 21:15'	System	03 Oct 2020 01:15:11

FDA-CBER-2022-1614-3120110

US3742137
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120111

US3742137
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120112

US3742137
Folder: Diary Dose 2 (1)
Form: Headache_Day(9)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	01 Oct 2020 22:04:40
User entered 'Day 9'	System	01 Oct 2020 22:04:40

US3742137
Folder: Diary Dose 2 (1)
Form: Headache_Day(9)
Generated On: 10 Jun 2021 09:34:30
Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-03T18:56:11', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '3375391d-1034-4d4e-a9c1-1203eae847b1'	System	03 Oct 2020 22:56:17
User entered 'None (0)'	System	03 Oct 2020 22:56:17

FDA-CBER-2022-1614-3120114

US3742137
Folder: Diary Dose 2 (1)
Form: Headache_Day(9)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-03T18:56:14', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '3375391d-1034-4d4e-a9c1-1203eae847b1'	System	03 Oct 2020 22:56:17
User entered '03 Oct 2020 18:56'	System	03 Oct 2020 22:56:17

US3742137
Folder: Diary Dose 2 (1)
Form: Headache_Day(9)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120116

US3742137
Folder: Diary Dose 2 (1)
Form: Headache_Day(9)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120117

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	01 Oct 2020 02:54:09
User entered 'Day 8'	System	01 Oct 2020 02:54:09

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 10 Jun 2021 09:34:30
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-02T21:15:12', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '8647229c-301d-44bd-9a3b-66c9ac2f09fc'	System	03 Oct 2020 01:15:17
User entered 'No interference with activity (1)'	System	03 Oct 2020 01:15:17

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-02T21:15:15', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '8647229c-301d-44bd-9a3b-66c9ac2f09fc'	System	03 Oct 2020 01:15:17
User entered '02 Oct 2020 21:15'	System	03 Oct 2020 01:15:17

FDA-CBER-2022-1614-3120120

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 02:54:09

FDA-CBER-2022-1614-3120121

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 02:54:09

FDA-CBER-2022-1614-3120122

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	01 Oct 2020 22:04:40
User entered 'Day 9'	System	01 Oct 2020 22:04:40

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 10 Jun 2021 09:34:30
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-03T18:56:24', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'a7366384-3f22-456d-a567-547ef01a2d53'	System	03 Oct 2020 22:56:28
User entered 'No interference with activity (1)'	System	03 Oct 2020 22:56:28

FDA-CBER-2022-1614-3120124

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-03T18:56:25', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'a7366384-3f22-456d-a567-547ef01a2d53'	System	03 Oct 2020 22:56:28
User entered '03 Oct 2020 18:56'	System	03 Oct 2020 22:56:28

FDA-CBER-2022-1614-3120125

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120126

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120127

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(10)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	03 Oct 2020 01:15:17
User entered 'Day 10'	System	03 Oct 2020 01:15:17

FDA-CBER-2022-1614-3120128

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(10)
Generated On: 10 Jun 2021 09:34:30
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-04T16:28:16', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd7514557-19de-4db8-b543-fe5075b9a89a'	System	04 Oct 2020 20:28:20
User entered 'None (0)'	System	04 Oct 2020 20:28:20

FDA-CBER-2022-1614-3120129

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(10)
Generated On: 10 Jun 2021 09:34:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-04T16:28:19', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd7514557-19de-4db8-b543-fe5075b9a89a'	System	04 Oct 2020 20:28:20
User entered '04 Oct 2020 16:28'	System	04 Oct 2020 20:28:20

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(10)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 01:15:17

FDA-CBER-2022-1614-3120131

US3742137
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(10)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 01:15:17

FDA-CBER-2022-1614-3120132

US3742137
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	01 Oct 2020 22:04:40
User entered 'Day 8'	System	01 Oct 2020 22:04:40

US3742137
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 10 Jun 2021 09:34:30
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-02T21:15:20', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'bd3fe546-abe5-45a2-a477-3a4bd22ece6f'	System	03 Oct 2020 01:15:27
User entered 'None (0)'	System	03 Oct 2020 01:15:27

FDA-CBER-2022-1614-3120134

US3742137
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-02T21:15:22', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'bd3fe546-abe5-45a2-a477-3a4bd22ece6f'	System	03 Oct 2020 01:15:27
User entered '02 Oct 2020 21:15'	System	03 Oct 2020 01:15:27

FDA-CBER-2022-1614-3120135

US3742137
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120136

US3742137
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120137

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	01 Oct 2020 02:54:09
User entered 'Day 8'	System	01 Oct 2020 02:54:09

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-02T21:15:27', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'f6303a3f-118e-48c1-8098-b7809007bb73'	System	03 Oct 2020 01:15:33
User entered 'No (N)'	System	03 Oct 2020 01:15:33

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-02T21:15:29', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'f6303a3f-118e-48c1-8098-b7809007bb73'	System	03 Oct 2020 01:15:33
User entered '02 Oct 2020 21:15'	System	03 Oct 2020 01:15:33

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 02:54:09

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 02:54:09

FDA-CBER-2022-1614-3120142

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	01 Oct 2020 22:04:40
User entered 'Day 9'	System	01 Oct 2020 22:04:40

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-03T18:56:29', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '4a4c9036-1712-45cb-82b4-f6a0bd485b7b'	System	03 Oct 2020 22:56:35
User entered 'No (N)'	System	03 Oct 2020 22:56:35

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-03T18:56:31', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '4a4c9036-1712-45cb-82b4-f6a0bd485b7b'	System	03 Oct 2020 22:56:35
User entered '03 Oct 2020 18:56'	System	03 Oct 2020 22:56:35

FDA-CBER-2022-1614-3120145

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120146

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 22:04:40

FDA-CBER-2022-1614-3120147

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
DataPoint Activated.	System	03 Oct 2020 22:56:28
DataPoint Inactivated.	System	03 Oct 2020 22:56:17
Data entry locked.	System	03 Oct 2020 01:15:11
User entered 'Day 10'	System	03 Oct 2020 01:15:11

FDA-CBER-2022-1614-3120148

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 10 Jun 2021 09:34:30
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)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-04T16:28:22', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '3651b3da-f7df-479f-9e7c-37b733bd7fe1'	System	04 Oct 2020 20:28:25
User entered 'No (N)'	System	04 Oct 2020 20:28:25
DataPoint Activated.	System	03 Oct 2020 22:56:28
DataPoint Inactivated.	System	03 Oct 2020 22:56:17

FDA-CBER-2022-1614-3120149

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 10 Jun 2021 09:34:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-04T16:28:23', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '3651b3da-f7df-479f-9e7c-37b733bd7fe1'	System	04 Oct 2020 20:28:25
User entered '04 Oct 2020 16:28'	System	04 Oct 2020 20:28:25
DataPoint Activated.	System	03 Oct 2020 22:56:28
DataPoint Inactivated.	System	03 Oct 2020 22:56:17

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 10 Jun 2021 09:34:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
DataPoint Activated.	System	03 Oct 2020 22:56:28
DataPoint Inactivated.	System	03 Oct 2020 22:56:17
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 01:15:11

US3742137
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 10 Jun 2021 09:34:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
DataPoint Activated.	System	03 Oct 2020 22:56:28
DataPoint Inactivated.	System	03 Oct 2020 22:56:17
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 01:15:11

FDA-CBER-2022-1614-3120152

US3742137
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:46:05

US3742137
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:04:46
User entered '2 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 12:46:05

FDA-CBER-2022-1614-3120154

US3742137
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:04:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Oct 2020 12:46:05

US3742137
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:46
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 12:46:05

FDA-CBER-2022-1614-3120156

US3742137
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:46:20

US3742137
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '1'	System	06 Oct 2020 12:46:20

US3742137
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:58
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	12 Oct 2020 12:49:22

US3742137
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:58
User entered '9 Oct 2020'	Sherry McCammon (b) (4)	12 Oct 2020 12:49:22

US3742137
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:58
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	12 Oct 2020 12:49:22

US3742137
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:58
User entered empty.	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 12:49:22

US3742137
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	12 Oct 2020 12:49:28

US3742137
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '1'	System	12 Oct 2020 12:49:28

US3742137
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:18
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	21 Oct 2020 17:17:30

US3742137
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:18
User entered '16 Oct 2020'	Hassan Haji (b) (4) (b) (4)	21 Oct 2020 17:17:30

US3742137
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:18
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4) (b) (4)	21 Oct 2020 17:17:30

US3742137
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:18
User entered empty.	Hassan Haji (b) (4) (b) (4)	21 Oct 2020 17:17:30

FDA-CBER-2022-1614-3120168

US3742137
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:14:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:23
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	21 Oct 2020 17:17:36

US3742137
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '1'	System	21 Oct 2020 17:17:36

US3742137
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 15:43:47

US3742137
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:05:46
User entered '22 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 15:43:47

FDA-CBER-2022-1614-3120172

US3742137
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:46
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Oct 2020 15:43:47

FDA-CBER-2022-1614-3120173

US3742137
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered 'VISIT3'	System	22 Oct 2020 15:43:47

FDA-CBER-2022-1614-3120174

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:05:56
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 15:44:00

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:05:56
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 15:44:00

FDA-CBER-2022-1614-3120176

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:05:56
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 15:44:00

FDA-CBER-2022-1614-3120177

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered empty.	System	22 Oct 2020 15:44:00

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:05:56
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 15:44:00

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:56
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 15:44:00

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:05:56
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 15:44:00

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:56
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 15:44:00

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered empty.	System	22 Oct 2020 15:44:00

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:56
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 15:44:00

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered empty.	System	22 Oct 2020 15:44:00

FDA-CBER-2022-1614-3120185

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:56
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 15:44:00

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered empty.	System	22 Oct 2020 15:44:00

FDA-CBER-2022-1614-3120187

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:56
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 15:44:00

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered empty.	System	22 Oct 2020 15:44:00

FDA-CBER-2022-1614-3120189

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35

FDA-CBER-2022-1614-3120190

US3742137
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35

FDA-CBER-2022-1614-3120191

US3742137
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:34:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 15:44:07

US3742137
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:34:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:02
User entered '22 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 15:44:07

FDA-CBER-2022-1614-3120193

US3742137
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 15:44:20

US3742137
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:06:08
User entered '22 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 15:44:20

US3742137
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:08
User entered '10:17'	(b) (4), (b) (6)	22 Oct 2020 15:44:20

US3742137
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '22 Oct 2020 10:17'	System	22 Oct 2020 15:44:20

US3742137
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 15:44:24

US3742137
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '1'	System	22 Oct 2020 15:44:24

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 64'	System	28 Aug 2020 18:01:54

US3742137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-28T02:46:26', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1bdf0414-8a54-412f-8706-25a2db5c7b53'	System	28 Oct 2020 06:46:42
User entered 'No (N)'	System	28 Oct 2020 06:46:42

US3742137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-28T02:46:35', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1bdf0414-8a54-412f-8706-25a2db5c7b53'	System	28 Oct 2020 06:46:42
User entered 'No (N)'	System	28 Oct 2020 06:46:42

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-10-28T02:46:39', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1bdf0414-8a54-412f-8706-25a2db5c7b53'	System	28 Oct 2020 06:46:42
User entered '28 Oct 2020 02:46:39'	System	28 Oct 2020 06:46:42

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 18:01:54

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 18:01:54

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 71'	System	28 Aug 2020 18:01:54

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US3742137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-11-05T18:58:13', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '06fd4032-3223-43b6-80d1-bdfeb126d0b6'	System	05 Nov 2020 23:58:39
User entered 'No (N)'	System	05 Nov 2020 23:58:39

US3742137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-11-05T18:58:32', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '06fd4032-3223-43b6-80d1-bdfeb126d0b6'	System	05 Nov 2020 23:58:39
User entered 'No (N)'	System	05 Nov 2020 23:58:39

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-11-05T18:58:37', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '06fd4032-3223-43b6-80d1-bdfeb126d0b6'	System	05 Nov 2020 23:58:39
User entered '05 Nov 2020 18:58:37'	System	05 Nov 2020 23:58:39

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 18:01:54

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 18:01:54

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered 'Day 78'	System	28 Aug 2020 18:01:54

US3742137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-11-11T14:24:41', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '4044904e-4c75-4323-8c8e-58332d5a56dc'	System	11 Nov 2020 19:24:51
User entered 'No (N)'	System	11 Nov 2020 19:24:51

US3742137

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-11-11T14:24:44', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '4044904e-4c75-4323-8c8e-58332d5a56dc'	System	11 Nov 2020 19:24:51
User entered 'No (N)'	System	11 Nov 2020 19:24:51

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-11-11T14:24:47', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '4044904e-4c75-4323-8c8e-58332d5a56dc'	System	11 Nov 2020 19:24:51
User entered '11 Nov 2020 14:24:47'	System	11 Nov 2020 19:24:51

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 18:01:54

US3742137
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:49:05
Data entry locked.	System	28 Aug 2020 18:01:54
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 18:01:54

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-11-22T11:50:40', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '5d17713d-3e93-4418-942d-e5e324c49c7b'	System	22 Nov 2020 16:50:50
User entered 'No (N)'	System	22 Nov 2020 16:50:50

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-11-22T11:50:44', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '5d17713d-3e93-4418-942d-e5e324c49c7b'	System	22 Nov 2020 16:50:50
User entered 'No (N)'	System	22 Nov 2020 16:50:50

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-11-22T11:50:46', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '5d17713d-3e93-4418-942d-e5e324c49c7b'	System	22 Nov 2020 16:50:50
User entered '22 Nov 2020 11:50:46'	System	22 Nov 2020 16:50:50

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-01T14:54:49', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '03ac1351-1fb9-4347-b5f6-c394fe520d89'	System	01 Dec 2020 19:55:16
User entered 'Yes (Y)'	System	01 Dec 2020 19:55:16

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-01T14:54:44', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '03ac1351-1fb9-4347-b5f6-c394fe520d89'	System	01 Dec 2020 19:55:16
User entered 'Yes (Y)'	System	01 Dec 2020 19:55:16

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Please 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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-01T14:54:43', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '03ac1351-1fb9-4347-b5f6-c394fe520d89'	System	01 Dec 2020 19:55:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Dec 2020 19:55:16

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-01T14:54:42', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '03ac1351-1fb9-4347-b5f6-c394fe520d89'	System	01 Dec 2020 19:55:16
User entered 'No (N)'	System	01 Dec 2020 19:55:16

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-01T14:54:55', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '03ac1351-1fb9-4347-b5f6-c394fe520d89'	System	01 Dec 2020 19:55:16
User entered 'No (N)'	System	01 Dec 2020 19:55:16

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-01T14:55:05', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '03ac1351-1fb9-4347-b5f6-c394fe520d89'	System	01 Dec 2020 19:55:16
User entered '01 Dec 2020 14:55:05'	System	01 Dec 2020 19:55:16

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-06T15:10:34', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '46b3be08-7578-4092-98df-08e593e1f698'	System	06 Dec 2020 20:10:46
User entered 'No (N)'	System	06 Dec 2020 20:10:46

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-06T15:10:41', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '46b3be08-7578-4092-98df-08e593e1f698'	System	06 Dec 2020 20:10:46
User entered 'No (N)'	System	06 Dec 2020 20:10:46

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-06T15:10:44', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '46b3be08-7578-4092-98df-08e593e1f698'	System	06 Dec 2020 20:10:46
User entered '06 Dec 2020 15:10:44'	System	06 Dec 2020 20:10:46

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-13T23:12:42', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '808ec1b5-6591-496e-8349-44ffba4d0c07'	System	14 Dec 2020 04:12:53
User entered 'No (N)'	System	14 Dec 2020 04:12:53

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-13T23:12:45', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '808ec1b5-6591-496e-8349-44ffba4d0c07'	System	14 Dec 2020 04:12:53
User entered 'No (N)'	System	14 Dec 2020 04:12:53

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-13T23:12:48', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '808ec1b5-6591-496e-8349-44ffba4d0c07'	System	14 Dec 2020 04:12:53
User entered '13 Dec 2020 23:12:48'	System	14 Dec 2020 04:12:53

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-20T10:55:06', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1c1ae75c-1a86-4daa-ad61-a2a35547eaee'	System	20 Dec 2020 15:55:15
User entered 'No (N)'	System	20 Dec 2020 15:55:15

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-20T10:55:09', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1c1ae75c-1a86-4daa-ad61-a2a35547eaee'	System	20 Dec 2020 15:55:15
User entered 'No (N)'	System	20 Dec 2020 15:55:15

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-20T10:55:12', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '1c1ae75c-1a86-4daa-ad61-a2a35547eaee'	System	20 Dec 2020 15:55:15
User entered '20 Dec 2020 10:55:12'	System	20 Dec 2020 15:55:15

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-27T09:40:43', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd90be9c6-c29b-4752-bc51-ec254e4edee0'	System	27 Dec 2020 14:40:54
User entered 'No (N)'	System	27 Dec 2020 14:40:54

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-27T09:40:49', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd90be9c6-c29b-4752-bc51-ec254e4edee0'	System	27 Dec 2020 14:40:54
User entered 'No (N)'	System	27 Dec 2020 14:40:54

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2020-12-27T09:40:51', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd90be9c6-c29b-4752-bc51-ec254e4edee0'	System	27 Dec 2020 14:40:54
User entered '27 Dec 2020 09:40:51'	System	27 Dec 2020 14:40:54

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2021-01-03T09:47:14', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ce76d240-1b72-4f07-8c55-64bc23f57763'	System	03 Jan 2021 14:47:51
User entered 'Yes (Y)'	System	03 Jan 2021 14:47:51

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2021-01-03T09:47:18', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ce76d240-1b72-4f07-8c55-64bc23f57763'	System	03 Jan 2021 14:47:51
User entered 'No (N)'	System	03 Jan 2021 14:47:51

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2021-01-03T09:47:22', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ce76d240-1b72-4f07-8c55-64bc23f57763'	System	03 Jan 2021 14:47:51
User entered 'No (N)'	System	03 Jan 2021 14:47:51

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2021-01-03T09:47:30', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ce76d240-1b72-4f07-8c55-64bc23f57763'	System	03 Jan 2021 14:47:51
User entered 'Yes (Y)'	System	03 Jan 2021 14:47:51

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Please 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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2021-01-03T09:47:36', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ce76d240-1b72-4f07-8c55-64bc23f57763'	System	03 Jan 2021 14:47:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Jan 2021 14:47:51

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2021-01-03T09:47:39', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'ce76d240-1b72-4f07-8c55-64bc23f57763'	System	03 Jan 2021 14:47:51
User entered '03 Jan 2021 09:47:39'	System	03 Jan 2021 14:47:51

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2021-01-11T16:13:10', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '27b15319-936a-401c-8c95-a0da44c6bc10'	System	11 Jan 2021 21:13:18
User entered 'No (N)'	System	11 Jan 2021 21:13:18

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2021-01-11T16:13:13', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '27b15319-936a-401c-8c95-a0da44c6bc10'	System	11 Jan 2021 21:13:18
User entered 'No (N)'	System	11 Jan 2021 21:13:18

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2021-01-11T16:13:15', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '27b15319-936a-401c-8c95-a0da44c6bc10'	System	11 Jan 2021 21:13:18
User entered '11 Jan 2021 16:13:15'	System	11 Jan 2021 21:13:18

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2021-01-17T09:57:34', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e4841302-80bc-4863-9db9-ed724e1f71eb'	System	17 Jan 2021 14:57:44
User entered 'No (N)'	System	17 Jan 2021 14:57:44

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2021-01-17T09:57:40', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e4841302-80bc-4863-9db9-ed724e1f71eb'	System	17 Jan 2021 14:57:44
User entered 'No (N)'	System	17 Jan 2021 14:57:44

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D418CF56-74BD-4FA2-B33B-C2B939DC9219)', Time: '2021-01-17T09:57:43', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'e4841302-80bc-4863-9db9-ed724e1f71eb'	System	17 Jan 2021 14:57:44
User entered '17 Jan 2021 09:57:43'	System	17 Jan 2021 14:57:44

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-01-24T20:23:25', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'da413f5a-49ba-4592-997d-44a58c8b135e'	System	25 Jan 2021 01:23:56
User entered 'Yes (Y)'	System	25 Jan 2021 01:23:56

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-01-24T20:23:31', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'da413f5a-49ba-4592-997d-44a58c8b135e'	System	25 Jan 2021 01:23:56
User entered 'No (N)'	System	25 Jan 2021 01:23:56

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-01-24T20:23:36', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'da413f5a-49ba-4592-997d-44a58c8b135e'	System	25 Jan 2021 01:23:56
User entered 'No (N)'	System	25 Jan 2021 01:23:56

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-01-24T20:23:40', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'da413f5a-49ba-4592-997d-44a58c8b135e'	System	25 Jan 2021 01:23:56
User entered 'Yes (Y)'	System	25 Jan 2021 01:23:56

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Please 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-01-24T20:23:43', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'da413f5a-49ba-4592-997d-44a58c8b135e'	System	25 Jan 2021 01:23:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 01:23:56

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-01-24T20:23:47', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'da413f5a-49ba-4592-997d-44a58c8b135e'	System	25 Jan 2021 01:23:56
User entered '24 Jan 2021 20:23:47'	System	25 Jan 2021 01:23:56

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-01-31T18:49:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '73f3c84f-a966-486a-b80f-263b576bbb1f'	System	31 Jan 2021 23:49:09
User entered 'No (N)'	System	31 Jan 2021 23:49:09

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-01-31T18:49:04', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '73f3c84f-a966-486a-b80f-263b576bbb1f'	System	31 Jan 2021 23:49:09
User entered 'No (N)'	System	31 Jan 2021 23:49:09

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-01-31T18:49:06', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '73f3c84f-a966-486a-b80f-263b576bbb1f'	System	31 Jan 2021 23:49:09
User entered '31 Jan 2021 18:49:06'	System	31 Jan 2021 23:49:09

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-07T15:27:44', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '7c54e561-0ef0-4bee-a87e-30b0be59c565'	System	07 Feb 2021 20:27:54
User entered 'No (N)'	System	07 Feb 2021 20:27:54

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-07T15:27:49', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '7c54e561-0ef0-4bee-a87e-30b0be59c565'	System	07 Feb 2021 20:27:54
User entered 'No (N)'	System	07 Feb 2021 20:27:54

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-07T15:27:51', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '7c54e561-0ef0-4bee-a87e-30b0be59c565'	System	07 Feb 2021 20:27:54
User entered '07 Feb 2021 15:27:51'	System	07 Feb 2021 20:27:54

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-14T17:53:25', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '99e04f30-145a-4b83-b021-23e517bb2e65'	System	14 Feb 2021 22:53:34
User entered 'No (N)'	System	14 Feb 2021 22:53:34

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-14T17:53:27', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '99e04f30-145a-4b83-b021-23e517bb2e65'	System	14 Feb 2021 22:53:34
User entered 'No (N)'	System	14 Feb 2021 22:53:34

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-14T17:53:29', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '99e04f30-145a-4b83-b021-23e517bb2e65'	System	14 Feb 2021 22:53:34
User entered '14 Feb 2021 17:53:29'	System	14 Feb 2021 22:53:34

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-21T11:20:58', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2669315d-6a97-45f2-93e9-39e5dfb55745'	System	21 Feb 2021 16:21:09
User entered 'No (N)'	System	21 Feb 2021 16:21:09

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-21T11:21:01', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2669315d-6a97-45f2-93e9-39e5dfb55745'	System	21 Feb 2021 16:21:09
User entered 'No (N)'	System	21 Feb 2021 16:21:09

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-21T11:21:06', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2669315d-6a97-45f2-93e9-39e5dfb55745'	System	21 Feb 2021 16:21:09
User entered '21 Feb 2021 11:21:06'	System	21 Feb 2021 16:21:09

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-28T10:05:49-05:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '7723c640-1610-4379-975a-55db62e57010'	System	28 Feb 2021 15:05:56
User entered 'No (N)'	System	28 Feb 2021 15:05:56

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-28T10:05:52-05:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '7723c640-1610-4379-975a-55db62e57010'	System	28 Feb 2021 15:05:56
User entered 'No (N)'	System	28 Feb 2021 15:05:56

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-28T10:05:54-05:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '7723c640-1610-4379-975a-55db62e57010'	System	28 Feb 2021 15:05:56
User entered '28 Feb 2021 10:05:54'	System	28 Feb 2021 15:05:56

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-07T14:53:46-05:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '11eb587a-5d63-4d7f-873e-18a07f3820e1'	System	07 Mar 2021 19:53:54
User entered 'No (N)'	System	07 Mar 2021 19:53:54

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-07T14:53:49-05:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '11eb587a-5d63-4d7f-873e-18a07f3820e1'	System	07 Mar 2021 19:53:54
User entered 'No (N)'	System	07 Mar 2021 19:53:54

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-07T14:53:51-05:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '11eb587a-5d63-4d7f-873e-18a07f3820e1'	System	07 Mar 2021 19:53:54
User entered '07 Mar 2021 14:53:51'	System	07 Mar 2021 19:53:54

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-14T16:25:01-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0e02e830-48aa-4552-984a-3f990885984f'	System	14 Mar 2021 20:25:08
User entered 'No (N)'	System	14 Mar 2021 20:25:08

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-14T16:25:04-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0e02e830-48aa-4552-984a-3f990885984f'	System	14 Mar 2021 20:25:08
User entered 'No (N)'	System	14 Mar 2021 20:25:08

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-14T16:25:05-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '0e02e830-48aa-4552-984a-3f990885984f'	System	14 Mar 2021 20:25:08
User entered '14 Mar 2021 16:25:05'	System	14 Mar 2021 20:25:08

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-22T10:37:15-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '6218ce9d-0c35-4306-8c7e-e607d7b1657b'	System	22 Mar 2021 14:37:47
User entered 'Yes (Y)'	System	22 Mar 2021 14:37:47

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-22T10:37:18-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '6218ce9d-0c35-4306-8c7e-e607d7b1657b'	System	22 Mar 2021 14:37:47
User entered 'No (N)'	System	22 Mar 2021 14:37:47

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-22T10:37:21-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '6218ce9d-0c35-4306-8c7e-e607d7b1657b'	System	22 Mar 2021 14:37:47
User entered 'No (N)'	System	22 Mar 2021 14:37:47

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-22T10:37:28-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '6218ce9d-0c35-4306-8c7e-e607d7b1657b'	System	22 Mar 2021 14:37:47
User entered 'Yes (Y)'	System	22 Mar 2021 14:37:47

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Please 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-22T10:37:33-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '6218ce9d-0c35-4306-8c7e-e607d7b1657b'	System	22 Mar 2021 14:37:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Mar 2021 14:37:47

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-22T10:37:35-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '6218ce9d-0c35-4306-8c7e-e607d7b1657b'	System	22 Mar 2021 14:37:47
User entered '22 Mar 2021 10:37:35'	System	22 Mar 2021 14:37:47

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-30T12:00:21-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '59312533-1a7d-4fc3-a988-47a1b352b2f7'	System	30 Mar 2021 16:00:42
User entered 'No (N)'	System	30 Mar 2021 16:00:42

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-30T12:00:23-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '59312533-1a7d-4fc3-a988-47a1b352b2f7'	System	30 Mar 2021 16:00:42
User entered 'No (N)'	System	30 Mar 2021 16:00:42

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-03-30T12:00:26-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '59312533-1a7d-4fc3-a988-47a1b352b2f7'	System	30 Mar 2021 16:00:42
User entered '30 Mar 2021 12:00:26'	System	30 Mar 2021 16:00:42

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-04-05T11:38:11-05:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'aa3989a5-3da6-499c-b6fc-22cce3c44aa8'	System	05 Apr 2021 16:38:54
User entered 'No (N)'	System	05 Apr 2021 16:38:54

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-04-05T11:38:13-05:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'aa3989a5-3da6-499c-b6fc-22cce3c44aa8'	System	05 Apr 2021 16:38:54
User entered 'No (N)'	System	05 Apr 2021 16:38:54

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-04-05T11:38:15-05:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'aa3989a5-3da6-499c-b6fc-22cce3c44aa8'	System	05 Apr 2021 16:38:54
User entered '05 Apr 2021 11:38:15'	System	05 Apr 2021 16:38:54

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-04-11T13:51:12-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '8d5a8516-c80e-4899-aa3e-57d7beb99d94'	System	11 Apr 2021 17:51:22
User entered 'No (N)'	System	11 Apr 2021 17:51:22

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-04-11T13:51:14-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '8d5a8516-c80e-4899-aa3e-57d7beb99d94'	System	11 Apr 2021 17:51:22
User entered 'No (N)'	System	11 Apr 2021 17:51:22

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-04-11T13:51:17-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '8d5a8516-c80e-4899-aa3e-57d7beb99d94'	System	11 Apr 2021 17:51:22
User entered '11 Apr 2021 13:51:17'	System	11 Apr 2021 17:51:22

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-04-19T08:13:45-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2ee6f860-68a8-43b1-adbd-4c62c53c6f8b'	System	19 Apr 2021 12:13:57
User entered 'No (N)'	System	19 Apr 2021 12:13:57

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-04-19T08:13:49-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2ee6f860-68a8-43b1-adbd-4c62c53c6f8b'	System	19 Apr 2021 12:13:57
User entered 'No (N)'	System	19 Apr 2021 12:13:57

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-04-19T08:13:53-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '2ee6f860-68a8-43b1-adbd-4c62c53c6f8b'	System	19 Apr 2021 12:13:57
User entered '19 Apr 2021 08:13:53'	System	19 Apr 2021 12:13:57

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-04-25T20:51:42-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '57e30584-200d-4895-84f8-a0c647a71ff1'	System	26 Apr 2021 00:51:51
User entered 'No (N)'	System	26 Apr 2021 00:51:51

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-04-25T20:51:44-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '57e30584-200d-4895-84f8-a0c647a71ff1'	System	26 Apr 2021 00:51:51
User entered 'No (N)'	System	26 Apr 2021 00:51:51

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-04-25T20:51:47-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: '57e30584-200d-4895-84f8-a0c647a71ff1'	System	26 Apr 2021 00:51:51
User entered '25 Apr 2021 20:51:47'	System	26 Apr 2021 00:51:51

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:48:19

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-05-02T08:51:54-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd5e2066d-edc4-4774-a649-55c754b846ea'	System	02 May 2021 12:52:03
User entered 'No (N)'	System	02 May 2021 12:52:03

US3742137

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:30

Have you been exposed to someone with 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 (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-05-02T08:51:58-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd5e2066d-edc4-4774-a649-55c754b846ea'	System	02 May 2021 12:52:03
User entered 'No (N)'	System	02 May 2021 12:52:03

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-05-02T08:52:00-04:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'd5e2066d-edc4-4774-a649-55c754b846ea'	System	02 May 2021 12:52:03
User entered '02 May 2021 08:52:00'	System	02 May 2021 12:52:03

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:48:19

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:48:19

US3742137
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:34:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:48:19
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:48:19

US3742137

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:34:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:45:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-28T10:06:15-05:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'acc7d6df-9068-43e9-8a84-a676647c4100'	System	28 Feb 2021 15:06:20
User entered 'No (N)'	System	28 Feb 2021 15:06:20

US3742137
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 10 Jun 2021 09:34:30
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:45:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94D0F6E0-A1C2-4961-856F-6A1F042FB21A)', Time: '2021-02-28T10:06:17-05:00', User OID: 'PatientReportedOutcome (US3742137)', ODM File OID: 'acc7d6df-9068-43e9-8a84-a676647c4100'	System	28 Feb 2021 15:06:20
User entered '28 Feb 2021 10:06:17'	System	28 Feb 2021 15:06:20

US3742137
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:47:57
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:39:54

FDA-CBER-2022-1614-3120610

US3742137
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:47:57
User entered '19 Nov 2020'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:39:54

US3742137
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:47:57
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:39:54

US3742137
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:47:57
User entered empty.	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:39:54

FDA-CBER-2022-1614-3120613

US3742137
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:24
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:40:23

US3742137
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:58:35
User entered '1'	System	19 Nov 2020 15:40:23

FDA-CBER-2022-1614-3120615

US3742137
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:02:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Dec 2020 14:42:32

US3742137
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:13:55
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:02:53
User entered '22 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:42:32

US3742137
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:02:53
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	23 Dec 2020 14:42:32

US3742137
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:13:55
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:02:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:42:32

FDA-CBER-2022-1614-3120619

US3742137
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:13:55
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:02:58
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:42:37

FDA-CBER-2022-1614-3120620

US3742137
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:13:55
User entered '1'	System	23 Dec 2020 14:42:37

US3742137
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:03:31
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Jan 2021 21:21:36

US3742137
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:13:55
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:03:31
User entered '21 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:21:36

US3742137
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:13:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:03:31
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	25 Jan 2021 21:21:36

US3742137
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:13:55
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:03:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:21:36

FDA-CBER-2022-1614-3120625

US3742137
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:13:55
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:03:37
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:21:42

US3742137
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:13:55
User entered '1'	System	25 Jan 2021 21:21:42

US3742137
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:23
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:26:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 15:00:48

FDA-CBER-2022-1614-3120628

US3742137
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:23
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:26:03
User entered '23 Feb 2021'	(b) (4), (b) (6)	03 Mar 2021 15:00:48

FDA-CBER-2022-1614-3120629

US3742137
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:23
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:26:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Mar 2021 15:00:48

US3742137
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:23
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:26:03
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 15:00:48

FDA-CBER-2022-1614-3120631

US3742137
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:23
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:26:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 15:00:55

FDA-CBER-2022-1614-3120632

US3742137
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:23
User entered '1'	System	03 Mar 2021 15:00:55

FDA-CBER-2022-1614-3120633

US3742137
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:16:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 14:01:12

FDA-CBER-2022-1614-3120634

US3742137
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:16:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered '23 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 14:01:12

FDA-CBER-2022-1614-3120635

US3742137
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
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 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:16:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Mar 2021 14:01:12

US3742137
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered 'VISIT4'	System	24 Mar 2021 14:01:12

FDA-CBER-2022-1614-3120637

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:56
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 19:14:00

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:56
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:14:00

FDA-CBER-2022-1614-3120639

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:56
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:14:00

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered empty.	System	30 Mar 2021 19:14:00

FDA-CBER-2022-1614-3120641

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:56
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:14:00

FDA-CBER-2022-1614-3120642

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:56
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:14:00

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:56
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:14:00

FDA-CBER-2022-1614-3120644

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:56
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:14:00

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered empty.	System	30 Mar 2021 19:14:00

FDA-CBER-2022-1614-3120646

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:56
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:14:00

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered empty.	System	30 Mar 2021 19:14:00

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:56
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:14:00

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered empty.	System	30 Mar 2021 19:14:00

FDA-CBER-2022-1614-3120650

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:56
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:14:00

FDA-CBER-2022-1614-3120651

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered empty.	System	30 Mar 2021 19:14:00

FDA-CBER-2022-1614-3120652

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24

FDA-CBER-2022-1614-3120653

US3742137
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24

FDA-CBER-2022-1614-3120654

US3742137
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:34:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 14:01:57

FDA-CBER-2022-1614-3120655

US3742137
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:34:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 14:01:57

FDA-CBER-2022-1614-3120656

US3742137
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:11
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 14:01:36

US3742137
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:11
User closed query 'Per GCL lab Recon: Per Preclarus report, this “Visit 04 Month 7” Immuno sample dated is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:32:48
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
Query 'Per GCL lab Recon: Per Preclarus report, this “Visit 04 Month 7” Immuno sample dated is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' answered with 'Collection date is correct. Accession # 1F60D7I' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:15:54
User opened query 'Per GCL lab Recon: Per Preclarus report, this “Visit 04 Month 7” Immuno sample dated is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:59:04
User entered '23 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 14:01:36

US3742137
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:11
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered '13:12'	(b) (4), (b) (6)	24 Mar 2021 14:01:36

US3742137
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered '23 Mar 2021 13:12'	System	24 Mar 2021 14:01:36

US3742137
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:20
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 14:01:45

FDA-CBER-2022-1614-3120661

US3742137
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:56:24
User entered '1'	System	24 Mar 2021 14:01:45

FDA-CBER-2022-1614-3120662

US3742137
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	23 Apr 2021 17:54:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 15:01:12

US3742137
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	23 Apr 2021 17:54:08
User entered '22 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 15:01:12

US3742137
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:54:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:01:12

US3742137
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:34:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	23 Apr 2021 17:54:08
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 15:01:12

FDA-CBER-2022-1614-3120666

US3742137
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	23 Apr 2021 17:54:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 15:01:31

US3742137
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:34:30
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 15:01:31

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:34:30
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:03
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:20
User entered '30 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:35:38

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:34:30
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:03
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:20
User entered '13:05'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:35:38

FDA-CBER-2022-1614-3120670

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:34:30
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:03
User entered '30 Nov 2020 13:05'	System	10 Dec 2020 16:35:38

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:34:30
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:20
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:35:38

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:34:30
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:20
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	10 Dec 2020 16:35:38

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User entered 'Day 1 (Day 1)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:35

FDA-CBER-2022-1614-3120674

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '26 Nov 2020'	Sherry McCammon (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '0'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:06:25
User closed query 'Per CDM: It appears that O2 was not collected for Days 1-4. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 19:30:51
Query 'Per CDM: It appears that O2 was not collected for Days 1-4. If not collected, please consider recording as Not Done.' answered with 'ND-NOT DONE ADDED' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:50:50
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:50:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:50:31
User opened query 'Per CDM: It appears that O2 was not collected for Days 1-4. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 15:42:52
Query 'Per CDM: It appears that O2 was not collected. If not collected, please consider recording as Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 15:41:06
User opened query 'Per CDM: It appears that O2 was not collected. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 15:40:54
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:35

FDA-CBER-2022-1614-3120677

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User entered '%'	System	25 Jan 2021 17:50:31
User entered empty.	System	10 Dec 2020 16:37:35

FDA-CBER-2022-1614-3120678

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '100.9' F reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:45:14
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:35

FDA-CBER-2022-1614-3120681

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:45:48
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:35

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:47:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:47:55
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:35

FDA-CBER-2022-1614-3120692

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:54:32
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:35

FDA-CBER-2022-1614-3120693

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:54:32
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:35

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (1)
Generated On: 10 Jun 2021 09:34:30
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:35

FDA-CBER-2022-1614-3120695

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User entered 'Day 2 (Day 2)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '27 Nov 2020'	Sherry McCammon (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '0'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:25
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:50:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:50:31
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User entered '%'	System	25 Jan 2021 17:50:31
User entered empty.	System	10 Dec 2020 16:37:50

FDA-CBER-2022-1614-3120700

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '100.9' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:45:14
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:50

FDA-CBER-2022-1614-3120701

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:45:48
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:50

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:47:10
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:47:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:54:32
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:50

FDA-CBER-2022-1614-3120715

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:54:32
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:37:50

FDA-CBER-2022-1614-3120716

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (2)
Generated On: 10 Jun 2021 09:34:30
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:50

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User entered 'Day 3 (Day 3)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '28 Nov 2020'	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '0'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:25
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:50:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:50:31
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

FDA-CBER-2022-1614-3120721

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User entered '%'	System	25 Jan 2021 17:50:31
User entered empty.	System	10 Dec 2020 16:38:07

FDA-CBER-2022-1614-3120722

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '100.0' F reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:45:14
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:07

FDA-CBER-2022-1614-3120724

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

FDA-CBER-2022-1614-3120727

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:45:48
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:47:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:47:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

FDA-CBER-2022-1614-3120735

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

FDA-CBER-2022-1614-3120736

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:54:32
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

FDA-CBER-2022-1614-3120737

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:54:32
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

FDA-CBER-2022-1614-3120738

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (3)
Generated On: 10 Jun 2021 09:34:30
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:07

FDA-CBER-2022-1614-3120739

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
User closed query 'Per CDM: Per sponsor review, please confirm Symptom Day as 28Nov2020 is also recorded as Day 3. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 16:41:20
Query 'Per CDM: Per sponsor review, please confirm Symptom Day as 28Nov2020 is also recorded as Day 3. ' answered with 'changed 29Nov2020 to day 4' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 18:41:25
Signature has been broken.	(b) (4), (b) (6)	24 Mar 2021 18:41:08
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 18:41:08
User opened query 'Per CDM: Per sponsor review, please confirm Symptom Day as 28Nov2020 is also recorded as Day 3. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 20:21:33
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User entered 'Day 3 (Day 3)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '29 Nov 2020'	Sherry McCammon (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '0'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:20

FDA-CBER-2022-1614-3120742

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:25
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:50:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:50:31
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:20

FDA-CBER-2022-1614-3120743

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User entered '%'	System	25 Jan 2021 17:50:31
User entered empty.	System	10 Dec 2020 16:38:20

FDA-CBER-2022-1614-3120744

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '99.8' F reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:45:14
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:50:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:45:48
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:20

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:47:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:20

FDA-CBER-2022-1614-3120754

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:47:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:38:20

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (4)
Generated On: 10 Jun 2021 09:34:30
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:38:20

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User entered 'Day 5 (Day 5)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:33

FDA-CBER-2022-1614-3120762

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '30 Nov 2020'	Sherry McCammon (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '0'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '99' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:43:15
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User entered '%'	System	10 Dec 2020 16:43:15
User entered empty.	System	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '98.2' F reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:45:14
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:51:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:51:30
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:33

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:01
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:45:48
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:33

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:47:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:47:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:33

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:33

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (5)
Generated On: 10 Jun 2021 09:34:30
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:33

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User entered 'Day 6 (Day 6)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:54

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '01 Dec 2020'	Sherry McCammon (b) (4)	10 Dec 2020 16:40:54

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '0'	Sherry McCammon (b) (4)	10 Dec 2020 16:40:54

FDA-CBER-2022-1614-3120786

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '99' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:43:15
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:54

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User entered '%'	System	10 Dec 2020 16:43:15
User entered empty.	System	10 Dec 2020 16:40:54

FDA-CBER-2022-1614-3120788

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '98.9' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:45:14
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:54

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:51:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:54

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:51:30
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:54

FDA-CBER-2022-1614-3120791

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:54

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:54

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:45:48
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:54

FDA-CBER-2022-1614-3120794

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:54

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:54

FDA-CBER-2022-1614-3120796

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:47:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:54

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:54

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:54

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:47:55
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:54

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:54

FDA-CBER-2022-1614-3120801

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:40:54

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:54

FDA-CBER-2022-1614-3120803

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:54

FDA-CBER-2022-1614-3120804

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (6)
Generated On: 10 Jun 2021 09:34:30
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:40:54

FDA-CBER-2022-1614-3120805

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User entered 'Day 7 (Day 7)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:22

FDA-CBER-2022-1614-3120806

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '02 Dec 2020'	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '0'	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '99' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:43:15
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User entered '%'	System	10 Dec 2020 16:43:15
User entered empty.	System	10 Dec 2020 16:41:22

FDA-CBER-2022-1614-3120810

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '99.3' F reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:45:14
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:51:30
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

FDA-CBER-2022-1614-3120812

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:51:30
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

FDA-CBER-2022-1614-3120813

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:01
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:47:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:47:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

FDA-CBER-2022-1614-3120820

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

FDA-CBER-2022-1614-3120821

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:47:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:22

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

FDA-CBER-2022-1614-3120825

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

FDA-CBER-2022-1614-3120826

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (7)
Generated On: 10 Jun 2021 09:34:30
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:22

FDA-CBER-2022-1614-3120827

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User entered 'Day 8 (Day 8)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:40

FDA-CBER-2022-1614-3120828

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '03 Dec 2020'	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '0'	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:43:15
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User entered '%'	System	10 Dec 2020 16:43:15
User entered empty.	System	10 Dec 2020 16:41:40

FDA-CBER-2022-1614-3120832

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '98.9' F reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:45:14
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:51:30
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:51:30
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

FDA-CBER-2022-1614-3120835

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:01
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

FDA-CBER-2022-1614-3120836

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:47:10
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

FDA-CBER-2022-1614-3120840

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:47:10
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

FDA-CBER-2022-1614-3120841

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:47:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (8)
Generated On: 10 Jun 2021 09:34:30
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:40

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User entered 'Day 9 (Day 9)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '04 Dec 2020'	Sherry McCammon (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '0'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:43:15
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User entered '%'	System	10 Dec 2020 16:43:15
User entered empty.	System	10 Dec 2020 16:41:55

FDA-CBER-2022-1614-3120854

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered '99.3' F reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:45:14
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:51:30
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:55

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:51:30
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:01
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:47:10
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:52:55
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:55

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:47:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:53:51
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:47:55
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:55:29
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:55

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Symptom Log (9)
Generated On: 10 Jun 2021 09:34:30
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:35
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:49:31
User entered empty.	Sherry McCammon (b) (4)	10 Dec 2020 16:41:55

FDA-CBER-2022-1614-3120871

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:34:30
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:25
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:43
User entered '30 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:36:16

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:34:30
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:25
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:43
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:36:16

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:34:30
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:25
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:43
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:36:16

FDA-CBER-2022-1614-3120874

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:34:30
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:25
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:43
User entered '30 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:36:16

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:34:30
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:43
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:36:16

FDA-CBER-2022-1614-3120876

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:34:30
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:25
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:43
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:36:16

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:34:30
Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:25
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:43
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:36:16

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:34:30
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:25
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:43
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:36:16

FDA-CBER-2022-1614-3120879

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:34:30
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:25
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:49:43
User entered empty.	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:36:16

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US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: COVID Diagnostic Test
Generated On: 10 Jun 2021 09:34:30
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:25
User entered '0'	System	10 Dec 2020 16:36:16

US3742137
Folder: Covid-19 Assessment 30 Nov 2020
Form: Generate Next COVID-19 Assessment
Generated On: 10 Jun 2021 09:34:30
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:59:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:50:02
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:37:16

FDA-CBER-2022-1614-3120882

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 10 Jun 2021 09:34:30
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User accepted default value 'Day 3 (Day 3)'	Sherry McCammon (b) (4) (b) (4)	03 Dec 2020 20:00:26

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 10 Jun 2021 09:34:30
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	03 Dec 2020 20:00:26

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 10 Jun 2021 09:34:30
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User entered '02 Dec 2020'	Sherry McCammon (b) (4)	03 Dec 2020 20:00:26

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 10 Jun 2021 09:34:30
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User accepted default value 'Day 5 (Day 5)'	Sherry McCammon (b) (4) (b) (4)	03 Dec 2020 20:00:26

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 10 Jun 2021 09:34:30
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:51:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	10 Dec 2020 16:59:06
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 16:28:35
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:28:30
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 19:40:12
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 11:58:15
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	Kaitlin Mason (b) (4) (b) (4)	04 Dec 2020 15:43:59
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 20:00:26
User entered empty.	Sherry McCammon (b) (4) (b) (4)	03 Dec 2020 20:00:26

FDA-CBER-2022-1614-3120887

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 10 Jun 2021 09:34:30
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:28:30
User closed query 'Please enter day 5 sample collection dated 04 Dec 2020' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:28:15
Query 'Please enter day 5 sample collection dated 04 Dec 2020' answered with 'updated' (Site from CRA).	Kaitlin Mason (b) (4)	09 Dec 2020 21:16:18
User entered '04 Dec 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Dec 2020 21:15:58
User opened query 'Please enter day 5 sample collection dated 04 Dec 2020' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 19:53:27
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 19:40:12
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User entered empty.	Sherry McCammon (b) (4)	03 Dec 2020 20:00:26

FDA-CBER-2022-1614-3120888

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 10 Jun 2021 09:34:30
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User accepted default value 'Day 7 (Day 7)'	Sherry McCammon (b) (4) (b) (4)	03 Dec 2020 20:00:26

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 10 Jun 2021 09:34:30
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:51:17
DataPoint Un-verified.	Sherry McCammon (b) (4)	10 Dec 2020 16:59:06
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:59:06
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 11:58:27
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	Kaitlin Mason (b) (4)	04 Dec 2020 15:44:07
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 20:00:26
User entered empty.	Sherry McCammon (b) (4)	03 Dec 2020 20:00:26

FDA-CBER-2022-1614-3120890

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 10 Jun 2021 09:34:30
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User entered empty.	Sherry McCammon (b) (4)	03 Dec 2020 20:00:26

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 10 Jun 2021 09:34:30
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User accepted default value 'Day 9 (Day 9)'	Sherry McCammon (b) (4) (b) (4)	03 Dec 2020 20:00:26

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 10 Jun 2021 09:34:30
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:51:17
DataPoint Un-verified.	Sherry McCammon (b) (4)	10 Dec 2020 16:59:06
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:59:06
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 11:58:39
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	Kaitlin Mason (b) (4)	04 Dec 2020 15:44:14
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 20:00:26
User entered empty.	Sherry McCammon (b) (4)	03 Dec 2020 20:00:26

FDA-CBER-2022-1614-3120893

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 10 Jun 2021 09:34:30
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	03 Dec 2020 20:00:26

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 10 Jun 2021 09:34:30
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User accepted default value 'Day 14 (Day 14)'	Sherry McCammon (b) (4) (b) (4)	03 Dec 2020 20:00:26

FDA-CBER-2022-1614-3120895

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 10 Jun 2021 09:34:30
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:51:17
DataPoint Un-verified.	Sherry McCammon (b) (4)	10 Dec 2020 16:59:06
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:59:06
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 11:59:02
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	Kaitlin Mason (b) (4)	04 Dec 2020 15:44:22
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 20:00:26
User entered empty.	Sherry McCammon (b) (4)	03 Dec 2020 20:00:26

FDA-CBER-2022-1614-3120896

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 10 Jun 2021 09:34:30
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User entered empty.	Sherry McCammon (b) (4)	03 Dec 2020 20:00:26

FDA-CBER-2022-1614-3120897

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 10 Jun 2021 09:34:30
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User accepted default value 'Day 21 (Day 21)'	Sherry McCammon (b) (4) (b) (4)	03 Dec 2020 20:00:26

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 10 Jun 2021 09:34:30
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:51:17
DataPoint Un-verified.	Sherry McCammon (b) (4)	10 Dec 2020 16:59:06
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:59:06
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 11:59:28
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	Kaitlin Mason (b) (4)	04 Dec 2020 15:44:30
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 20:00:26
User entered empty.	Sherry McCammon (b) (4)	03 Dec 2020 20:00:26

FDA-CBER-2022-1614-3120899

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 10 Jun 2021 09:34:30
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User entered empty.	Sherry McCammon (b) (4) (b) (4)	03 Dec 2020 20:00:26

FDA-CBER-2022-1614-3120900

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 10 Jun 2021 09:34:30
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User accepted default value 'Day 28 (Day 28)'	Sherry McCammon (b) (4) (b) (4)	03 Dec 2020 20:00:26

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 10 Jun 2021 09:34:30
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:51:17
DataPoint Un-verified.	Sherry McCammon (b) (4)	10 Dec 2020 16:59:06
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	10 Dec 2020 16:59:06
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 11:59:46
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	Kaitlin Mason (b) (4)	04 Dec 2020 15:44:37
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 20:00:26
User entered empty.	Sherry McCammon (b) (4)	03 Dec 2020 20:00:26

US3742137
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 10 Jun 2021 09:34:30
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:39:44
User entered empty.	Sherry McCammon (b) (4)	03 Dec 2020 20:00:26

FDA-CBER-2022-1614-3120903

US3742137
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:31:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:36:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 20:35:12

FDA-CBER-2022-1614-3120904

US3742137
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:31:50
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:36:43
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 20:35:12

FDA-CBER-2022-1614-3120905

US3742137
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:31:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:36:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Nov 2020 20:35:12

FDA-CBER-2022-1614-3120906

US3742137
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:31:50
User entered 'SICKD1'	System	30 Nov 2020 20:35:12

FDA-CBER-2022-1614-3120907

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 20:37:21

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:06
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 20:37:21

FDA-CBER-2022-1614-3120909

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:06
User entered '13:05'	(b) (4), (b) (6)	30 Nov 2020 20:37:21

FDA-CBER-2022-1614-3120910

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User entered '30 Nov 2020 13:05'	System	30 Nov 2020 20:37:21

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:06
User entered '65.0' in	(b) (4), (b) (6)	30 Nov 2020 20:37:21
DataPoint set to visible.	System	30 Nov 2020 20:35:12

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:06
User entered '171.0' lb	(b) (4), (b) (6)	30 Nov 2020 20:37:21
DataPoint set to visible.	System	30 Nov 2020 20:35:12

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:06
User entered '98.2' F	(b) (4), (b) (6)	30 Nov 2020 20:37:21

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Nov 2020 20:37:21

FDA-CBER-2022-1614-3120915

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:06
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:37:21

FDA-CBER-2022-1614-3120916

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:06
User entered '83'	(b) (4), (b) (6)	30 Nov 2020 20:37:21

FDA-CBER-2022-1614-3120917

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User entered 'bpm'	System	30 Nov 2020 20:37:21

FDA-CBER-2022-1614-3120918

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:06
User entered '16'	(b) (4), (b) (6)	30 Nov 2020 20:37:21

FDA-CBER-2022-1614-3120919

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User entered 'breaths/min'	System	30 Nov 2020 20:37:21

FDA-CBER-2022-1614-3120920

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:06
User entered '130'	(b) (4), (b) (6)	30 Nov 2020 20:37:21

FDA-CBER-2022-1614-3120921

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User entered 'mmHg'	System	30 Nov 2020 20:37:21

FDA-CBER-2022-1614-3120922

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:06
User entered '80'	(b) (4), (b) (6)	30 Nov 2020 20:37:21

FDA-CBER-2022-1614-3120923

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02
User entered 'mmHg'	System	30 Nov 2020 20:37:21

FDA-CBER-2022-1614-3120924

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02

FDA-CBER-2022-1614-3120925

US3742137
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:34:30
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:02

FDA-CBER-2022-1614-3120926

US3742137
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:34:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 20:37:54

FDA-CBER-2022-1614-3120927

US3742137
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:34:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:14
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 20:37:54

FDA-CBER-2022-1614-3120928

US3742137
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 10 Jun 2021 09:34:30
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 20:38:42

US3742137
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 10 Jun 2021 09:34:30
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:32:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:38:22
User entered '30 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 20:38:42

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 17:28:10

FDA-CBER-2022-1614-3120931

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:28
User entered '27 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 17:28:10

FDA-CBER-2022-1614-3120932

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Jan 2021 17:28:10

FDA-CBER-2022-1614-3120933

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:34:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 17:28:10

FDA-CBER-2022-1614-3120934

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:34:30
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:13:17
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:39:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:07
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 15:53:07
User entered '27 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 15:53:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:43
User entered '6 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 17:31:18

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:34:30
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:13:17
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:39:01
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 15:53:07
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:52:28

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:34:30
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 17:31:18

FDA-CBER-2022-1614-3120937

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:34:30
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:13:17
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:39:01
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:53:07
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:52:28

FDA-CBER-2022-1614-3120938

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:34:30
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:43
User entered '27 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 17:31:18

FDA-CBER-2022-1614-3120939

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:34:30
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:43
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	28 Jan 2021 17:31:18

FDA-CBER-2022-1614-3120940

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:34:30
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:43
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	28 Jan 2021 17:31:18

FDA-CBER-2022-1614-3120941

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:34:30
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:43
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	28 Jan 2021 17:31:18

FDA-CBER-2022-1614-3120942

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:34:30
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:43
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 17:31:18

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:34:30
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User entered empty.	System	28 Jan 2021 17:31:18

FDA-CBER-2022-1614-3120944

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:34:30
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User entered empty.	System	28 Jan 2021 17:31:18

FDA-CBER-2022-1614-3120945

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 17:29:45

FDA-CBER-2022-1614-3120946

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:50
User entered '27 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 17:29:45

FDA-CBER-2022-1614-3120947

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:07:50
User entered '14:55'	(b) (4), (b) (6)	28 Jan 2021 17:29:45

FDA-CBER-2022-1614-3120948

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:34:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User entered '27 Jan 2021 14:55'	System	28 Jan 2021 17:29:45

FDA-CBER-2022-1614-3120949

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:34:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:08:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 17:30:01

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:34:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:08:14
User entered '27 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 17:30:01

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:34:30
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:08:14
User entered '14:59'	(b) (4), (b) (6)	28 Jan 2021 17:30:01

FDA-CBER-2022-1614-3120952

US3742137
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:34:30
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:11
User entered '27 Jan 2021 14:59'	System	28 Jan 2021 17:30:01

FDA-CBER-2022-1614-3120953

US3742137
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:34:30
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:24
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 131, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:28:03
Query 'Per DM CLR: Per Safety Follow-up Diary Day 131, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'as per participant, healthcare provider added new con medications. no actual visits reported, just medications added' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:28:49
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 131, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 20:53:14
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46

US3742137
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:34:30
Did the participant experience any adverse events?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 9) and HEADACHE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 10:16:37
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 9) and HEADACHE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'Fatigue added to AE, defer adding HA as end day is day 8' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 20:05:06
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 9) and HEADACHE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 14:22:32
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:09:32
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:55

FDA-CBER-2022-1614-3120955

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14

FDA-CBER-2022-1614-3120956

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 03:31:52
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'Action taken refers to IP (investigational product)' (Site from DM).	Toni Robinson (b) (4) (b) (4)	22 Oct 2020 18:02:59
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:56:55
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:53:48
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:53:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Aural disorders NEC, HLT: Ear disorders NEC, PT: Ear pain, LLT: Otalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 14:42:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 14:42:41

FDA-CBER-2022-1614-3120957

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Adverse event

Audit	User	Time (GMT)
Data point term sent to Coder	System	28 Sep 2020 14:41:56
User entered 'OTALGIA'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered '22 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User entered empty.	System	28 Sep 2020 14:41:31

FDA-CBER-2022-1614-3120964

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Sep 2020 14:43:03
User entered '26 Sep 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:43:03
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Sep 2020 14:41:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

FDA-CBER-2022-1614-3120966

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User entered empty.	System	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:56:44
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:54:04
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered 'None (NONE)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:22:05
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed #12 that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:30:31
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed #12 that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'Updated' (Site from DM).	Toni Robinson (b) (4)	23 Oct 2020 10:42:42
DataPoint Un-verified.	Toni Robinson (b) (4)	23 Oct 2020 10:42:32
User entered '0' reason for change: Data Entry Error	Toni Robinson (b) (4)	23 Oct 2020 10:42:32
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed #12 that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 03:32:02
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered '1'	Sherry McCammon (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:22:05
DataPoint Un-verified.	Toni Robinson (b) (4) (b) (4)	23 Oct 2020 10:42:32
User entered '1' reason for change: Data Entry Error	Toni Robinson (b) (4) (b) (4)	23 Oct 2020 10:42:32
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered '0'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 14:43:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 14:43:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:43:03
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 14:41:31
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

FDA-CBER-2022-1614-3120987

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:05
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:00
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User entered '0'	System	28 Sep 2020 14:41:31

FDA-CBER-2022-1614-3120990

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14
User entered '1'	System	28 Sep 2020 14:41:31

US3742137
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:34:30
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:14

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28

FDA-CBER-2022-1614-3120993

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Nov 2020 20:31:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Nov 2020 20:31:59
Data point term sent to Coder	System	30 Nov 2020 20:31:24
User entered 'upper respiratory infection'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3120995

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3120996

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered '26 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3120998

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3120999

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User entered empty.	System	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
DataPoint Un-verified.	Sherry McCammon (b) (4)	23 Dec 2020 14:45:18
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 14:45:18
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
DataPoint Un-verified.	Sherry McCammon (b) (4)	23 Dec 2020 14:45:18
User entered '03 Dec 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 14:45:18
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User entered empty.	System	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3121004

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3121007

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3121009

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3121010

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3121011

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3121012

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

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US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered '1'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3121021

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered '0'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
DataPoint Un-verified.	Sherry McCammon (b) (4)	23 Dec 2020 14:45:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 14:45:18
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:48:36
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3121025

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User entered '0'	System	30 Nov 2020 20:31:16

FDA-CBER-2022-1614-3121026

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28
User entered '1'	System	30 Nov 2020 20:31:16

US3742137
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:34:30
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:50:28

FDA-CBER-2022-1614-3121028

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53

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US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 21:25:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 21:25:56
Data point term sent to Coder	System	25 Jan 2021 21:25:46
User entered 'TINNITUS'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 21:27:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 21:27:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 21:27:37
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 21:25:07
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:30:30
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	23 Apr 2021 17:54:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 15:05:51
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 15:05:51
User entered '20 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 15:05:51
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered '21 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User entered empty.	System	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:30:30
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	23 Apr 2021 17:54:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 15:05:51
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 15:05:51
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Apr 2021 15:05:51
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:30:30
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	23 Apr 2021 17:54:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 15:05:51
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 15:05:51
User entered '1 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	23 Apr 2021 15:05:51
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

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US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User entered empty.	System	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 21:27:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 21:27:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 21:27:37
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 21:25:07
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered '0'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered '0'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered '0'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

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US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered '0'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered '0'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered '0'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 21:27:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 21:27:37
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 21:27:37
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 21:25:07
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 21:27:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 21:27:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 21:27:37
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 21:25:07
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 21:27:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 21:27:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 21:27:37
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 21:25:07
User entered empty.	Sherry McCammon (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered '1'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered '0'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered '0'	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:30:30
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	23 Apr 2021 17:54:08
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	23 Apr 2021 15:19:09
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	(b) (4), (b) (6)	23 Apr 2021 15:19:09
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	23 Apr 2021 15:18:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	23 Apr 2021 15:18:03
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 15:05:51
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 15:05:51
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	(b) (4), (b) (6)	23 Apr 2021 15:05:51
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 21:27:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 21:27:37
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 21:27:37
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 21:25:07
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:30:30
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	23 Apr 2021 17:54:08
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	23 Apr 2021 15:18:03
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 15:18:03
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 15:18:03
User entered 'THE TINNITUS IS RELATED TO HER MIGRAINE HEADACHES. THE TINNITUS WILL RECUR WITH HER CHRONIC MIGRAINES.' reason for change: New Information	(b) (4), (b) (6)	23 Apr 2021 15:18:03
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	23 Apr 2021 15:05:51
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

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US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:04:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User entered '0'	System	03 Feb 2021 21:27:37

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53
User entered '1'	System	25 Jan 2021 21:25:07

US3742137
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:34:30
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:53

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US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55

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US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 13:42:07
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Subject was not assessed for COVID 19 here but later assess on 30 Nov 2020' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:55:15
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 19:36:31
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 17:19:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 17:19:55
Data point term sent to Coder	System	26 Feb 2021 17:18:49
User entered 'fatigue'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '25 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Feb 2021 19:19:19
User entered '19:23' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	26 Feb 2021 19:19:19
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Feb 2021 17:18:25
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

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US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
User entered '25 Sep 2020 19:23'	System	26 Feb 2021 19:19:19
User entered empty.	System	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '4 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	16 Mar 2021 18:06:36
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
Query 'Data is required. Please provide.' answered with 'NA' (Site from System).	Kaitlin Mason (b) (4) (b) (4)	26 Feb 2021 19:19:28
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Feb 2021 17:18:25
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

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US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
User entered empty.	System	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'Related (RELATED)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '1'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'prolonged vaccine reactogenicity'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
User entered '0'	System	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55
User entered '0'	System	26 Feb 2021 17:18:25

US3742137
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:34:30
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:55:55

FDA-CBER-2022-1614-3121100

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:57:24
User entered 'USA-US127-2021-mRNA-1273-P301000013'	System	01 Mar 2021 16:56:33
User entered 'New'	(b) (4), (b) (6)	01 Mar 2021 16:56:33

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Anaphylactic and anaphylactoid responses, PT: Anaphylactic reaction, LLT: Anaphylaxis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 17:36:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Feb 2021 17:36:56
Data point term sent to Coder	System	26 Feb 2021 17:20:55
User entered 'anaphylaxis'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '9 Feb 2021'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '9 Feb 2021'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

FDA-CBER-2022-1614-3121110

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
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	26 Feb 2021 17:26:34
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	26 Feb 2021 17:20:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:26:34
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:26:46
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 22:58:00
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Event was due to Antigen Challenge Allergy testing' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 22:48:01
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 22:46:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 22:46:50
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	01 Mar 2021 22:46:50
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	28 Feb 2021 23:59:11
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 17:20:11
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 22:58:03
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Event was due to Antigen Challenge Allergy testing' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 22:48:06
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 22:46:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 22:46:50
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	01 Mar 2021 22:46:50
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	28 Feb 2021 23:59:26
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 17:20:11
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 22:46:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Mar 2021 22:46:50
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	01 Mar 2021 22:46:50
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 17:20:11
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User closed query 'PV Query: Please correct start and stop dates for concomitant medications, Benadryl and epinephrine, in EDC. It was entered as 08 Feb 2021 but the event occurred on 09 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 14:33:36
Query 'PV Query: Please correct start and stop dates for concomitant medications, Benadryl and epinephrine, in EDC. It was entered as 08 Feb 2021 but the event occurred on 09 Feb 2021.' answered with 'corrected' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 16:08:32
User opened query 'PV Query: Please correct start and stop dates for concomitant medications, Benadryl and epinephrine, in EDC. It was entered as 08 Feb 2021 but the event occurred on 09 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 11:15:02
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User closed query 'PV Query: Please correct start and stop dates for concomitant medications, Benadryl and epinephrine, in EDC. It was entered as 08 Feb 2021 but the event occurred on 09 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 16:00:15
Query 'PV Query: Please correct start and stop dates for concomitant medications, Benadryl and epinephrine, in EDC. It was entered as 08 Feb 2021 but the event occurred on 09 Feb 2021.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 17:14:12
User opened query 'PV Query: Please correct start and stop dates for concomitant medications, Benadryl and epinephrine, in EDC. It was entered as 08 Feb 2021 but the event occurred on 09 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 12:28:12
User entered '1'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

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US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 17:22:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 17:22:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:22:11
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 17:20:11
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:13:27
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:26:46
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Feb 2021 17:25:48
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	26 Feb 2021 17:25:48
User entered 'PARTICIPANT HAD ALLERGY TESTING ON 09FEB2021 BECAUSE SHE HAS A HISTORY OF ASTHMA. DURING TESTING HAD AN ALLERGIC REACTION AND WAS GIVEN BENEDRYL,(LIQUID) EPINEPRHRINE (INJECTION). DOSES UNKNOWN.' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:25:48
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Feb 2021 17:20:11
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 17:20:11

US3742137
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:34:30
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 17:20:11

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 10 Jun 2021 09:34:30
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:24
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:10:11
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:50:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: XANAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:52:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:52:35
Data point term sent to Coder	System	11 Sep 2020 17:51:45
User entered 'XANAX'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'ANXIETY'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0.5'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'as needed (PRN)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '14 Dec 2010'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

FDA-CBER-2022-1614-3121147

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:51:31

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:53:40
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 Sep 2020 17:53:40
Data point term sent to Coder	System	11 Sep 2020 17:52:49
User entered 'ZOFRAN'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'NAUSEA'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '8'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'as needed (PRN)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

FDA-CBER-2022-1614-3121162

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '14 Dec 2010'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

FDA-CBER-2022-1614-3121168

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:52:32

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:54:45
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 Sep 2020 17:54:45
Data point term sent to Coder	System	11 Sep 2020 17:53:50
User entered 'SINGULAIR'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'ASTHMA'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '10'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'once daily (QD)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'UN Oct 2019'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

FDA-CBER-2022-1614-3121183

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:53:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:54:44
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 Sep 2020 17:54:44
Data point term sent to Coder	System	11 Sep 2020 17:53:50
User entered 'VALTREX'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'GENITAL HERPES'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '500'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'once daily (QD)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'UN Dec 2008'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:53:40

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:55:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:55:50
Data point term sent to Coder	System	11 Sep 2020 17:54:53
User entered 'ALBUTEROL'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'ASTHMA'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '1'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'puff (PUFF)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'as needed (PRN)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'UN UNK 1998'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:54:28

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:54:28

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 03:52:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 03:52:40
Data point term sent to Coder	System	11 Sep 2020 17:59:17
User entered 'TUMS [CALCIUM CARBONATE]'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'INDIGESTION'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '750'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'as needed (PRN)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

FDA-CBER-2022-1614-3121233

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

FDA-CBER-2022-1614-3121234

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'UN UNK 1998'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

FDA-CBER-2022-1614-3121237

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

FDA-CBER-2022-1614-3121240

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:58:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 09:13:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 09:13:36
Data point term sent to Coder	System	11 Sep 2020 17:55:56
User entered 'CLARITIN'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'ASTHMA'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '5'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'once daily (QD)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'UN Oct 2019'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

FDA-CBER-2022-1614-3121256

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:55:20

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
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)	29 Oct 2020 18:29:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:29:44
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
Data point term sent to Coder	System	28 Oct 2020 15:55:51
Coding entries removed.	(b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered 'IBUPROFEN' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:54:53
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)	12 Sep 2020 00:19:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 00:19:46
Data point term sent to Coder	System	11 Sep 2020 17:55:59
User entered 'IBUPROPHEN'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'GENERALIZED PAIN'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '800'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'as needed (PRN)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'UN UNK 2019'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:55:56

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:58:45
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 Sep 2020 17:58:45
Data point term sent to Coder	System	11 Sep 2020 17:57:10
User entered 'TYLENOL'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'GENERALIZED PAIN'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '1000'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'as needed (PRN)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

FDA-CBER-2022-1614-3121287

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

FDA-CBER-2022-1614-3121288

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'un UNK 1998'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

FDA-CBER-2022-1614-3121294

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 17:56:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 17:59:48
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 Sep 2020 17:59:48
Data point term sent to Coder	System	11 Sep 2020 17:58:14
User entered 'MELATONIN'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'INSOMNIA'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '3'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'once daily (QD)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'UN UNK 2015'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 17:57:53

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
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)	29 Oct 2020 18:28:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:28:02
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
Data point term sent to Coder	System	28 Oct 2020 15:50:31
Coding entries removed.	(b) (4), (b) (6)	28 Oct 2020 15:49:52
User entered 'IBUPROFEN' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:49:52
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)	14 Sep 2020 16:01:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:01:44
Data point term sent to Coder	System	14 Sep 2020 15:52:49
User entered 'IBUPROPHEN'	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the Pain at Injection Site is considered a solicited local or systemic adverse reaction, and meets any of the following criteria results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Pain at Injection Site did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 15:01:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the Pain at Injection Site is considered a solicited local or systemic adverse reaction, and meets any of the following criteria results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Pain at Injection Site did not meet the AE reporting criteria.' answered with 'Solicited reaction and not an AE' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:57:46

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the Pain at Injection Site is considered a solicited local or systemic adverse reaction, and meets any of the following criteria results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Pain at Injection Site did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:46:41
User entered 'PAIN AT INJECTION SITE'	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '800'	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'four times daily (QID)'	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

FDA-CBER-2022-1614-3121325

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '28 Aug 2020'	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:56:27
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:56:27
User entered empty.	Kaitlin Mason (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:56:27
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User entered '4'	System	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User entered '1'	System	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:31
User entered '804 (804)'	System	14 Sep 2020 15:52:13

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 08:50:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 08:50:48
Data point term sent to Coder	System	28 Sep 2020 14:38:50
User entered 'SUDAFED'	Sherry McCammon (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'OTALGIA'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '60'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'as needed (PRN)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '22 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Sherry McCammon (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '23 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User entered empty.	System	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User entered empty.	System	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:46
User entered empty.	System	28 Sep 2020 14:38:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:24:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:24:26
Data point term sent to Coder	System	05 Oct 2020 17:23:47
User entered 'ACETAMINOPHEN'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 15:00:08
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' answered with 'Did not meet AE criteria ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	13 Nov 2020 18:28:11

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 02:36:21
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'FEVER'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '1000'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'once daily (QD)'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

FDA-CBER-2022-1614-3121363

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User closed query 'Per DM CLR: Please review Start date of this medication as this is prior to Fever which started 26 SEP 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 15:00:50
Query 'Per DM CLR: Please review Start date of this medication as this is prior to Fever which started 26 SEP 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' answered with 'med taken by participant during documented date ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	13 Nov 2020 18:28:45
User opened query 'Per DM CLR: Please review Start date of this medication as this is prior to Fever which started 26 SEP 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 02:36:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '25 Sep 2020'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '27 Sep 2020'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User entered '1'	System	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User entered '1'	System	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:41
User entered '804 (804)'	System	05 Oct 2020 17:23:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
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)	05 Oct 2020 17:26:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:26:20
Data point term sent to Coder	System	05 Oct 2020 17:24:49
User entered 'IBUPROFEN'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 15:01:26
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'Did not meet AE criteria ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	13 Nov 2020 18:29:06

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 02:37:42
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'HEADACHE'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '800'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'once daily (QD)'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

FDA-CBER-2022-1614-3121382

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '25 Sep 2020'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered '27 Sep 2020'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 18:21:35
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User entered '1'	System	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User entered '1'	System	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:35
User entered '804 (804)'	System	05 Oct 2020 17:24:02

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:06:01
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)	23 Dec 2020 16:02:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 16:02:44
Data point term sent to Coder	System	23 Dec 2020 14:44:15
User entered 'INFLUENZA VACCINE'	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'FLU INFLUENZA'	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered '0.5'	Sherry McCammon (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'mL (mL)'	Sherry McCammon (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'once (ONCE)'	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'Intramuscular (INTRAMUSCULAR)'	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered '27 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered '0'	Sherry McCammon (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'No (N)'	Sherry McCammon (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered '27 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User entered empty.	System	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User entered empty.	System	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:47:07
User entered empty.	System	23 Dec 2020 14:44:04

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 16:46:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 16:46:41
Data point term sent to Coder	System	06 Jan 2021 16:46:01
Coding entries removed.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:45:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 16:45:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 16:45:42
Data point term sent to Coder	System	06 Jan 2021 16:45:00
User entered 'LISINOPRIL'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:45:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 16:45:48
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:45:48
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:44:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:45:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 16:45:48
User entered 'HYPERTENSION' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:45:48
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:44:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:45:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 16:45:48
User entered '10' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:45:48
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:44:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:45:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 16:45:48
User entered 'mg (mg)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:45:48
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:44:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:45:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 16:45:48
User entered 'once daily (QD)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:45:48
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:44:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:45:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 16:45:48
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:45:48
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:44:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Jan 2021 16:46:01
User entered '31 Dec 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:01
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Jan 2021 16:44:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered '0'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:45:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 16:45:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:45:48
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:44:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:45:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 16:45:48
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:45:48
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 16:44:59
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 16:45:48
User entered empty.	System	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 16:45:48
User entered empty.	System	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 16:45:48
User entered empty.	System	06 Jan 2021 16:44:59

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 16:47:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 16:47:41
Data point term sent to Coder	System	06 Jan 2021 16:47:01
User entered 'TRAZADONE'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'INSOMNIA'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered '50'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'mg (mg)'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'as needed (PRN)'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered '31 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered '0'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

FDA-CBER-2022-1614-3121440

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:18:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 17:06:01
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	06 Jan 2021 16:46:54

FDA-CBER-2022-1614-3121442

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 16:46:54

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 10:45:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 10:45:12
Data point term sent to Coder	System	26 Feb 2021 17:30:13
User entered 'EPINEPRHIRNE'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:17
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:18
User entered 'ANAPHYLAXIS'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:21
User entered '0.30'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:23
User entered 'mg (mg)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:28
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:16:26
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	26 Feb 2021 19:22:07
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	26 Feb 2021 17:30:08
User entered 'once (ONCE)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:29
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	26 Feb 2021 19:22:07
User entered ' '	Sherry McCammon (b) (4)	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:31
User entered 'Intramuscular (INTRAMUSCULAR)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:38
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:40
User closed query 'Per DM CLR: Please note that Con Med start date (8 FEB 2021) is prior to the start date of the corresponding AE (9 FEB 2021). Please review and reconcile the Con Med and AE start dates and correct as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:53:29
Query 'Per DM CLR: Please note that Con Med start date (8 FEB 2021) is prior to the start date of the corresponding AE (9 FEB 2021). Please review and reconcile the Con Med and AE start dates and correct as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 16:06:29
User entered '9 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 16:06:14
User opened query 'Per DM CLR: Please note that Con Med start date (8 FEB 2021) is prior to the start date of the corresponding AE (9 FEB 2021). Please review and reconcile the Con Med and AE start dates and correct as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:11:48
Query 'PV Query: Please correct start and stop dates for concomitant medications, Benadryl and epinephrine, in EDC. It was entered as 08 Feb 2021 but the event occurred on 09 Feb 2021' canceled (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 11:14:25
User opened query 'PV Query: Please correct start and stop dates for concomitant medications, Benadryl and epinephrine, in EDC. It was entered as 08 Feb 2021 but the event occurred on 09 Feb 2021' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 20:35:22
User entered '8 Feb 2021'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:43
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:45
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:47
User entered '9 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 16:06:14
User entered '8 Feb 2021'	Sherry McCammon (b) (4)	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:16:49
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:30:08

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User entered empty.	System	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User entered empty.	System	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:58
User entered empty.	System	26 Feb 2021 17:30:08

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:38:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:38:57
Data point term sent to Coder	System	26 Feb 2021 17:32:14
User entered 'BENEDRYL'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:29
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:31
User entered 'ANAPHYLAXIS'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:34
User entered '10'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:36
User entered 'mg (mg)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:37
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:39
User entered 'once (ONCE)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:40
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

FDA-CBER-2022-1614-3121471

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:42
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:45
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:44
User closed query 'Per DM CLR: Please note that Con Med start date (8 FEB 2021) is prior to the start date of the corresponding AE (9 FEB 2021). Please review and reconcile the Con Med and AE start dates and correct as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:53:38
Query 'Per DM CLR: Please note that Con Med start date (8 FEB 2021) is prior to the start date of the corresponding AE (9 FEB 2021). Please review and reconcile the Con Med and AE start dates and correct as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 16:07:52
User entered '9 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 16:07:44
User opened query 'Per DM CLR: Please note that Con Med start date (8 FEB 2021) is prior to the start date of the corresponding AE (9 FEB 2021). Please review and reconcile the Con Med and AE start dates and correct as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:12:17
Query 'PV Query: Please correct start and stop dates for concomitant medications, Benadryl and epinephrine, in EDC. It was entered as 08 Feb 2021 but the event occurred on 09 Feb 2021' canceled (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 11:14:31
User opened query 'PV Query: Please correct start and stop dates for concomitant medications, Benadryl and epinephrine, in EDC. It was entered as 08 Feb 2021 but the event occurred on 09 Feb 2021' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 20:35:42
User entered '8 Feb 2021'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:55
User entered '0'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:56
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:58
User entered '9 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 16:07:44
User entered '8 Feb 2021'	Sherry McCammon (b) (4)	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:59
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:31:43

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User entered empty.	System	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User entered empty.	System	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:46:53
User entered empty.	System	26 Feb 2021 17:31:43

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of MIGRAINE HEADACHES worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:30:45
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of MIGRAINE HEADACHES worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'No AE recorded for worsening migraine headaches. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 16:47:42
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of MIGRAINE HEADACHES worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:54:25
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:14:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 13:57:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 13:57:37
Data point term sent to Coder	System	24 Mar 2021 13:55:19
User entered 'Sumatriptan succinate'	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:14:43
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:14:45
User entered 'Migraine Headaches'	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:14:49
User entered '100'	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:14:47
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:14:50
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:14:52
User entered 'other (OTHER)'	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:14:54
User entered 'As needed'	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:14:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:14:57
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:14:59
User entered '17 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 13:54:44

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:01
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:03
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 13:54:44

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US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:15:05
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:34:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 13:54:44

US3742137
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 09:34:30
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:24
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:17:14
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:27:37

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US3742137
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:34:30
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:19:30
User entered '9 Feb 2021'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:28:05

US3742137
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:34:30
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:19:30
User entered 'ALLERGY TESTING DUE TO ASTHMA'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:28:05

US3742137
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:34:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:19:30
User entered 'Medical History (MH)'	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:28:05

US3742137
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:34:30
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:19:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	26 Feb 2021 17:28:05

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US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'USA-US127-2021-MRNA-1273-P301000013'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Yes (Y)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Death

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Yes (Y)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Karen'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Kotloff'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered '685 W. Baltimore Street, HSF 480'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Baltimore'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 13:51:02
Un-reviewed for Safety.	System	01 Mar 2021 23:03:22
User entered empty.	System	01 Mar 2021 23:03:22
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered 'MD'	(b) (4), (b) (6)	01 Mar 2021 21:22:22

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US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered '21201'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered 'US'	System	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 14:33:55
User entered '4'	System	10 Mar 2021 16:01:02
User entered '3'	System	02 Mar 2021 13:51:44
User entered '2'	System	01 Mar 2021 23:03:22
User entered '1'	System	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'USA-US127-2021-MRNA-1273-P301000013'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Yes (Y)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Death

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Yes (Y)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Karen'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Kotloff'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered '685 W. Baltimore Street, HSF 480'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Baltimore'	System	01 Mar 2021 16:56:33

FDA-CBER-2022-1614-3121532

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 13:51:02
Un-reviewed for Safety.	System	01 Mar 2021 23:03:22
User entered empty.	System	01 Mar 2021 23:03:22
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered 'MD'	(b) (4), (b) (6)	01 Mar 2021 21:22:22

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered '21201'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered 'US'	System	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 14:33:55
User entered '4'	System	10 Mar 2021 16:01:02
User entered '3'	System	02 Mar 2021 13:51:44
User entered '2'	System	01 Mar 2021 23:03:22
User entered '1'	System	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 09:34:30
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:29
User entered '01/Mar/2021 11:58'	System	01 Mar 2021 16:58:09

US3742137

Folder: SAE USA-US127-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:34:30

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.

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered '1'	(b) (4), (b) (6)	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'USA-US127-2021-MRNA-1273-P301000013'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Yes (Y)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Death

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Yes (Y)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Karen'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Kotloff'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered '685 W. Baltimore Street, HSF 480'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Baltimore'	System	01 Mar 2021 16:56:33

FDA-CBER-2022-1614-3121550

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 13:51:02
Un-reviewed for Safety.	System	01 Mar 2021 23:03:22
User entered empty.	System	01 Mar 2021 23:03:22
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered 'MD'	(b) (4), (b) (6)	01 Mar 2021 21:22:22

FDA-CBER-2022-1614-3121551

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered '21201'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered 'US'	System	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 14:33:55
User entered '4'	System	10 Mar 2021 16:01:02
User entered '3'	System	02 Mar 2021 13:51:44
User entered '2'	System	01 Mar 2021 23:03:22
User entered '1'	System	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 09:34:30
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:29
User entered '01/Mar/2021 18:03'	System	01 Mar 2021 23:03:22

US3742137

Folder: SAE USA-US127-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:34:30

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.

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 13:51:02
User entered '1'	(b) (4), (b) (6)	01 Mar 2021 23:03:22

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'USA-US127-2021-MRNA-1273-P301000013'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Yes (Y)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Death

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Yes (Y)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Karen'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Kotloff'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered '685 W. Baltimore Street, HSF 480'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Baltimore'	System	01 Mar 2021 16:56:33

FDA-CBER-2022-1614-3121568

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 13:51:02
Un-reviewed for Safety.	System	01 Mar 2021 23:03:22
User entered empty.	System	01 Mar 2021 23:03:22
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered 'MD'	(b) (4), (b) (6)	01 Mar 2021 21:22:22

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered '21201'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered 'US'	System	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 14:33:55
User entered '4'	System	10 Mar 2021 16:01:02
User entered '3'	System	02 Mar 2021 13:51:44
User entered '2'	System	01 Mar 2021 23:03:22
User entered '1'	System	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 09:34:30
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
User entered '02/Mar/2021 07:51'	System	02 Mar 2021 13:51:44

US3742137

Folder: SAE USA-US127-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:34:30

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.

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
User entered '1'	(b) (4), (b) (6)	02 Mar 2021 13:51:44

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'USA-US127-2021-MRNA-1273-P301000013'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Yes (Y)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Death

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Yes (Y)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Karen'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Kotloff'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered '685 W. Baltimore Street, HSF 480'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Baltimore'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 13:51:02
Un-reviewed for Safety.	System	01 Mar 2021 23:03:22
User entered empty.	System	01 Mar 2021 23:03:22
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered 'MD'	(b) (4), (b) (6)	01 Mar 2021 21:22:22

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered '21201'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered 'US'	System	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 14:33:55
User entered '4'	System	10 Mar 2021 16:01:02
User entered '3'	System	02 Mar 2021 13:51:44
User entered '2'	System	01 Mar 2021 23:03:22
User entered '1'	System	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 09:34:30
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:15:01
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:07:27
User entered '10/Mar/2021 08:01'	System (b) (4)	10 Mar 2021 16:01:02

US3742137

Folder: SAE USA-US127-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:34:30

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:15:01
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
User entered '1'	(b) (4), (b) (6)	10 Mar 2021 16:01:02

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'USA-US127-2021-MRNA-1273-P301000013'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Yes (Y)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Death

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Yes (Y)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'No (N)'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Karen'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Kotloff'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered '685 W. Baltimore Street, HSF 480'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered 'Baltimore'	System	01 Mar 2021 16:56:33

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 13:51:02
Un-reviewed for Safety.	System	01 Mar 2021 23:03:22
User entered empty.	System	01 Mar 2021 23:03:22
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered 'MD'	(b) (4), (b) (6)	01 Mar 2021 21:22:22

FDA-CBER-2022-1614-3121605

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:58:02
User entered '21201'	System	01 Mar 2021 16:56:33

FDA-CBER-2022-1614-3121606

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:26:29
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 23:03:00
User entered 'US'	System	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 10 Jun 2021 09:34:30
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 14:33:55
User entered '4'	System	10 Mar 2021 16:01:02
User entered '3'	System	02 Mar 2021 13:51:44
User entered '2'	System	01 Mar 2021 23:03:22
User entered '1'	System	01 Mar 2021 16:58:09

US3742137
Folder: SAE USA-US127-2021-MRNA-1273-P301000013
Form: Safety Report Form (5)
Generated On: 10 Jun 2021 09:34:30
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:15:08
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
User entered '24/Mar/2021 10:33'	System	24 Mar 2021 14:33:55

US3742137

Folder: SAE USA-US127-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:34:30

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:15:08
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	07 Apr 2021 21:07:27
User entered '1'	(b) (4), (b) (6)	24 Mar 2021 14:33:55